A STUDY TO ASSESS THE EFFECTIVENESS OF CLUSTERED CARE ON PHYSIOLOGICAL PARAMETERS, STRESS LEVEL AND COMFORT AMONG PRETERM NEWBORN ADMITTED IN NICU IN TERTIARY CARE SETTINGS, COIMBATORE

By

JEYAMONI.D

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A STUDY TO ASSESS THE EFFECTIVENESS OF CLUSTERED CARE ON PHYSIOLOGICAL PARAMETERS, SRESS LEVEL AND COMFORT AMONG PRETERM NEBORN ADMITTED IN NICU IN TERTIARY CARE SETTINGS, COIMBATORE

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ABSTRACT

A study to assess the effectiveness of clustered care on physiological parameters, stress and comfort level among preterm newborn admitted in NICU tertiary care setting, Coimbatore

Background of the study: Preterm newborns are under different procedures as a part of their care in the Neonatal Intensive Care Unit. The percentage of preterm deliveries born at 32 to 36 weeks gestation has risen steadily over the last 2 decades. Reduction of preterm newborn's stress, promotion of their comfort, and maintaining normal physiological parameters (Heart rate, Respiratory rate, and oxygen saturation) is pivotal. In order to reduce the stress clustered care is recommended.

Objective: The main objective of the study was to assess the effectiveness of clustered care on physiological parameters, stress and comfort level among preterm newborn.

Methods: A Quasi experimental multiple time series design with repeated institution of treatment was adopted .Forty preterm newborn were selected by purposive sampling method. In this 20 preterm newborn on phototherapy and another 20 for preterm care were provided clustered care. The study was conducted in Level II NICU. The demographic data were collected from medical records. The effect of clustered care was evaluate on stress, physiological parameters, and comfort level through modified NISS scale, pulse oxymeter and modified comfort score. Pretest was assessed 3 times for one day. Then the posttest was assessed thrice in a day for three days.

Result of the study: The finding showed there was no significant difference in mean of Heart rate before and after cluster care with four to six procedures. There was significant difference in Respiratory Rate and Oxygen saturation (SpO_2) with $p<0.001$ for both the groups. The comfort score for alertness ranged from slightly asleep 2(2-2) state to deeply asleep 1(1-1) and from anxious state 3(3-4) to calm state1 (1-1) and in Physical movement from frequent slight movement 3(2-3) to no movement 1(1-1) significant difference was found in comfort level for both the groups ($p<0.001$). The NISS score before and after clustered care for three days was statistically significant for both groups ($p<0.001$).

Conclusion: The study concludes clustered care on preterm newborn helps to reduce the stress and improve the comfort level thereby the normal physiological parameters were maintained.

Key words: Preterm newborn, Phototherapy, Physiological Parameters, Comfort, Clustered care.

CHAPTER - I

INTRODUCTION

1.1 Background of the study

Preterm birth creates challenges in management for all health care providers. They are not physiologically or developmentally prepared for life outside environment of the mother's womb. Their response to stimuli is often immature and disorganized rather than adaptive. (**Ciagnacco, 2015).**

Preterm newborn are commonly admitted in Neonatal Intensive Care Unit to uphold specialized medical attention, allowing time for immature organs to further develop. Neonatal Intensive Care Unit is stressful to the Preterm newborns from the moment of birth. Stressors in the Neonatal Intensive Care Unit are associated with alterations in the brain structure and functions of preterm newborn. Many studies found that preterm newborn who experienced early exposure to stress, later they displayed decreased brain size, irregular brain functional connectivity, and abnormal motor behavior. The studies have shown that up to 20% of preterm newborn (22-32 weeks) of gestation have cerebral palsy, nearly 40% display mild motor deficiency and up to 60% experience cognitive impairments, social difficulties and emotional issues. While interventional studies have demonstrated that exposure to stressors in the Neonatal Intensive Care Unit, may be harmful. Reducing stress in preterm newborn can improve the outcomes of brain development. (**Susan Cha and Saba W. Masho, 2011).**

Neonatal Care has risen year on year and currently pre term newborn accounts for >70% of admissions in NICU. The Neonatal Intensive Care Unit of the preterm newborn become mechanical or “robotic” and “stereotyped” instead of being flexible and individualized, technological advances have dehumanized to care of preterm newborns. Hi-tech care should be provided, but comfort of the newborns should not be ignored. Newborns should be reared in Neonatal Intensive Care Unit which should simulate the ecology of the womb, to ensure maximum comfort to the newborn. **(Sajina Sathian., 2014).**

A recent study showed that in India in tertiary care centers, less than 1000 grams of preterm newborns are surviving through long stay in Neonatal Intensive Care Unit. Among this 40% of preterm newborns are affected from neuron-developmental impairment**.** Preterm newborns are under different procedures as a part of their care in the Neonatal Intensive Care Unit. Reduction of their stress, promoting comfort, and improving the physiological parameters is pivotal. **(Sudan Chaudhari, 2014).**

The percentage of preterm deliveries born at 32 to 36 weeks gestation has risen steadily over the last 2 decades. The period of gestation is one of the most important predictors of an infant's subsequent health and survival. More than 5, 00, 00 newborns, (12.5 %) of all infants, were born as preterm in 2012 .which is considered birth at <37 completed weeks of gestation. Preterm birth is the major cause of neonatal mortality in developed and developing countries. Grouping of care in which the newborn is seen as the center of care and requires caregivers to act together, prioritizing the needs of the preterm newborn. This strategy also focuses on the importance of practicing clustered care and the importance of encouraging these practices within the Neonatal Intensive Care Unit**.(Stevens B, Yamada J.,2015)**

The Neonatal Intensive Care Unit environment has the potential to affect preterm newborn sleep both quality and quantity. Preterm newborns are often disturbed by frequent hands-on newborns care. The potential health and developmental impact of these disturbances strategies preventing by continuous monitor of newborn sleep and thus will minimize sleep-disordered, newborn breathing might then improve in Neonatal Intensive Care Unit .(**Wiley Periodicals, 2015).**

NICU can be a noisy place with noxious sounds like loud talking, banging of incubator doors, dropping of equipment on the floor, alarms etc… Preterm newborn are at a particular risk for sensory neural hearing loss with an incidence of 4-13% depending on their gestational age, as compared to 2% in all newborns. The US environment protective agency (EPA) has recommended a sound level of 45dB. Noise level in incubators is up to 50-80dB .Preterm newborn respond to this noise by increased heart rate, alterations in blood pressure and cerebral blood flow. They are in risk of increased stress level. Hence, the idea behind developmentally supportive care or clustered care is to create a ‘’womb out of womb" and aimed at decreasing the

stress of the preterm newborn in the NICU. The NIDCAP has lead to a greater emphasis on developmental care**.(sudha chaudhari 2015).**

In order to reduce the stress, and improve the comfort of preterm newborn many interventions are in practices, such as nesting, swaddling, cling wrap and musical therapy. One of the newer and important ways is clustered care, which is recommended for preterm newborn admitted in Neonatal Intensive Care Unit. To provide longer periods of rest. In fact some studies showed that clustered care is provides longer periods of rest for preterm newborn as a result they sleep more, gain more weight and have rapid reduction in apnea incidence. These advantages may be greater recommendation of clustered care as a strategy for reduction of their stress. Hence clustered care seems to be necessary in Neonatal Intensive Care Unit. (**Warren Bond., 2016).**

Sleep is decisive to brain maturation in preterm newborn. Deprivation of sleep (2-4 hours) in preterm newborn has been found to lead to short-term alterations in cardiac function during the next sleep cycle, and increased respiratory events (e.g., apnea). The importance of observing sleep-wake states in preterm and critically ill term newborn is to ensure that nursing care focuses on prevention or reduce of stress in the newborn. Providing timely competent nursing care protects newborn sleep in the Neonatal Intensive Care Unit. **(Kimberly A. Allen, 2017).**

Recent study stated that sleep disruption is increasingly recognized in hospitalized neonates. The neonatal intensive care unit (NICU) environment has the potential to affect sleep quality and quantity. Impaired sleep is associated with measureable alterations in neurodevelopment, so term and near-term neonates are at risk for cerebral dysfunction. Infants in the NICU experience frequent hands-on care, associated with disturbances of sleep and respiration. Minimal handling might improve the quality of preterm neonate's life in NICU **(Jennifer levy, 2017).**

1.2 Need for the study:

Over the past 20 years, developmental care has grown from a theory to a research and supported standard of care. Neonatal Intensive Care Units have embraced developmental care principles from newborn positioning, feeding, nesting and other nursing care too. Innovation in design to promote development must be paired with care giving practices that support individual infant competency and family integration. Therefore Neonatal Intensive Care Unit nurses need to have adequate experience, and skilful training towards preterm newborn care. **(Elizabeth Jeason, 2013).**

Nearly 20 million infants (15.5% of all births) worldwide, are born as low birth weight with preterm labor. The incidence being nearly twice (16.5%) in the developing world than the developed world(7%).India accounts for more than 40% of the overall load of the low birth across the globe. 7.5% million newborn being born annually. Thus constituting 30% of the total live births. These newborn are risk of poor long term neurodevelopment outcome during childhood. But prevention of their morbidity depends upon care provided in the neonatal intensive care. Simple measures to prevent morbidity must be exercised with emphasis on skilled practice on preterm care. In this regard developmental care or clustered care is recommended. **(Tapas Bandyopadhyay, 2014).**

Preterm newborn's sleep, comfort, minimum stress will improve the brain development and prevent the long term complications. The neonatal intensive care unit is the predominant behavioral state in the term and especially the preterm newborn, Sleep and wakefulness also have direct effects on brain function, and brain development of Newborns. As a health team members pay much attention to protecting newborn health, and incorporate the scientific rationale behind the preterm newborn wellbeing.

Clustered care is clustering several routine nursing care events together rather than spacing them out over time. The expanded review of national and international literature found that, Clustered care includes changing the diaper, measuring abdominal girth, taking the auxiliary temperature, mouth care, changing the position, orogastric feeding, placing the newborn under phototherapy, and checking of blood glucose of preterm neonates etc... The main

goal of clustered care is allowing the preterm newborn to have longer periods of rest and promote comfort. **(Solimano A,Little ford J,.2016).**

A randomized crossover clinical trial, on clustered care with 3 and 4 procedures recommends, to study clustering of care for more than 4 procedures, also the sleep/wake states and behavioral responses of preterm infants together with physiological responses. **(Leila Valizadeh, Marziyeh Avazeh, 2014).**

When I was posted clinical setting in NICU, I have observed that preterm newborns are disturbed more frequently for their routine care. Due to that preterm newborns undergone stress and their sleep gets altered. Light, noise, and handling of equipments in NICU setting also contributing stress to preterm newborn. In order to promote sleep and rest, minimal handling is essential. So the researcher was interested to study the effect of clustered care in preterm newborn. Hence the study was planned.

1.3 Statement of the Problem

A study to assess the Effectiveness of Clustered Care on Physiological Parameters, Stress and Comfort level among Preterm newborn admitted in NICU tertiary Care Setting, Coimbatore.

1.4 Objectives:

1. To assess the stress, physiological parameters, and comfort level of preterm newborn on phototherapy, and preterm care.
2. To observe the existing practice of nursing care given to preterm newborn on phototherapy and preterm care and form clusters at various time intervals.
3. To evaluate the effectiveness of clustered care on stress, physiological parameters, and comfort level among preterm newborn on phototherapy and preterm cares.
4. To evaluate the effectiveness of clustered care on stress, physiological parameters, and comfort level among neonates on preterm care.

1.5 Assumptions:

- NICU Preterm newborns are handled frequently due to various procedures.
- Minimal handling of preterm newborn may increase their comfort level.
- Adequate rest, sleep and comfort aids in maintenance of normal physiological parameters of preterm newborn.
- Clustered care may promote sleep, rest and weight gain.

1.6 Hypothesis:

H_1: There will be a significant difference in pre and posttest scores of stress among preterm newborn on phototherapy.

H_2: There will be a significant difference in pre and posttest scores of physiological parameters among preterm newborn on phototherapy.

H_3: There will be a significant difference in pre and posttest comfort scores of preterm newborn on phototherapy.

H_4: There will be a significant difference in pre and posttest scores of stress among neonates on preterm care.

H_5: There will be a significant difference in pre and posttest scores of physiological parameters among neonates on preterm care.

H_6: There will be a significant difference in pre and posttest comfort scores of neonates on preterm care.

1.7 Delimitations:

The study is delimited to

1. Preterm newborn born between 32-37weeks gestation
2. Preterm newborn admitted for phototherapy.
3. Preterm newborn admitted routine preterm care.

1.8 Operational definitions:

Assess:

It refers to the measuring the physiological parameters, stress and comfort level of preterm newborn on phototherapy and preterm care as measured by modified NISS scale and modified COMFORT scale.

Effectiveness:

It refers to the extent to which the clustered care reduces the stress, and maintains physiological parameters, and comfort of preterm newborn on phototherapy and preterm care, as measured by NISS and modified COMFORT scale.

Clustered care:

Clustered care is combining 4-5, procedures at a time as clusters at various shifts, to minimize frequent handling of newborn. In this study it refers to clustering formed in three shifts like morning, afternoon, and night.

Physiological parameter:

It refers to the heart rate, respiratory rate, and oxygen saturation of preterm newborn at various time intervals before and after clustered care as measured by pulse oxymeter.

Stress:

In this study it refers to the procedure imposed stress experienced by the preterm newborn with according to invasive and non invasive procedures performed from admission to 3 days period. It has been graded into 1- Not stressful, A little stressful-2, moderately stressful -3, Very stressful-4, and extremely stressful -5, as measured by NISS scale.

Comfort:

It refers to the level of Alertness ranging from deeply asleep to hyper alert and scored as 1-5. Calmness described as calm to panicky and scored as 1-5, and physical movement described as no movement to vigorous movements including torso and head scored as 1-5 of preterm newborn on phototherapy and preterm care before and after clustered care.

Preterm newborn:

It refers to the Preterm newborn admitted in the level II NICU born between 32-37 weeks of gestation admitted for phototherapy and preterm care such as thermoregulation, feeding, and weight promotion.

1.9 Projected Outcome:

Clustered care will be an effective method in reducing the stress, maintain the physiological parameters and promote the comfort among preterm newborn on phototherapy and preterm care.

1.10 Conceptual Framework:

Modified Wiedenbach's helping art of Clinical Nursing Theory is used as the conceptual framework to assess the effectiveness of stress, comfort and physiological parameters among preterm newborn those who are in clustered care.

The conceptual framework was developed by Ernestine Wiedenbach's in 1964.the theory has two parts. (a) Helping Art of Clinical Nursing Theory and (b) Nursing Practice. Helping Art of Clinical Nursing Theory is prescriptive theory for nursing which describes a desired action and the ways to attain it. It consists of three factors, central purpose, prescription, and realities.

Central purpose: Refers to what the researcher wants to accomplish. It is the overall goal. It is the task of assignment directing towards the attainment of goal.

The central purpose of this study is to reduce the stress level, improve the comfort and maintaining the normal physiological parameters by clustered care.

In this study clustered care is used for the preterm newborn on phototherapy, preterm care, followed by the pre assessment of, stress, Physiological parameters and comfort level will be assessed for three days and three times per day.

Realities: It refers to the physical, physiologic and emotional factors that involves in nursing actions. In this theory there are five realities. They are as follows.

Agent: One who directs all action towards the goal and has capacities, commitment, and competence to provide care.

Researcher: Knowledge on clustered care and skill on cluster is forming, assessment of stress, physiological parameters and comfort level.Nurses who give clustered care to the preterm newborns.

Recipient: One who is vulnerable and dependent and receives all attention, here the preterm newborn on phototherapy, and preterm care during their stay in NICU.

Goals: It refers to the desired outcome of the action. It denotes reduction in stress level, maintains the normal physiological parameters improve the comfort, and was considered as the goal of the study.

Means:

- This refers to the activities used to achieve the goal**.**
- In this study the clustered care given to the preterm newborns for the reduction of stress.

Framework:

- It refers to the facility in which it is practiced.
- Here it refers to the level II, neonatal intensive care unit of PSG Hospital Coimbatore.
- Widenbach's consists of identification, administration, and validation

Identification:

- It refers to the viewing the indiduals unique experiences and perceptions.
- It refers to the selection of samples and the pre-assessment of the stress level physiological parameters, and comfort level response to clustered care.

Administration:

In this study it refers to the administration of clustered care to the preterm newborn on phototherapy, and preterm care.

Validation:

It refers to the restoration of the functional ability through the implementation of the action. Here it is the assessment of physiological parameters, stress level, and the comfort level before and after the clustered care of preterm newborn on phototherapy, and preterm care.

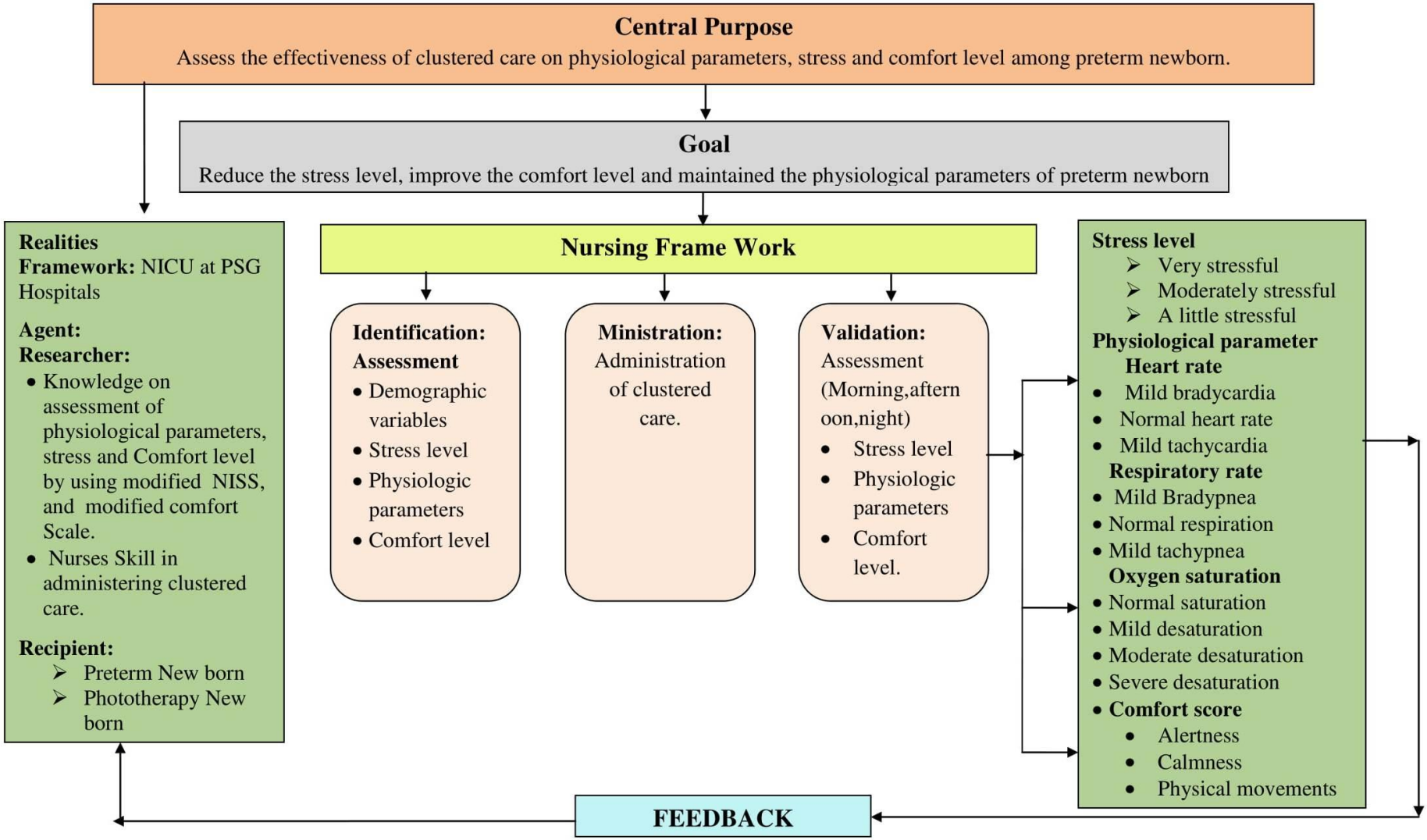

Figure-1: Modified Widenbach's prescriptive theory to assess the effectiveness of clustered care on physiological parameters, stress and comfort level among preterm new born.

Chapter summary:

This chapter dealt with background of the study, need for the study, and statement of the problem, objectives, assumptions, hypothesis, delimitations, operational definitions and conceptual frame work. The next chapters are organized as follows,

Chapter II - Literature Review

Chapter III - Materials and Method

Chapter IV - Data Analysis

Chapter V - Results and Discussion

Chapter VI - Summary and Conclusion.

CHAPTER-II

REVIEW OF LITRATURE

A review of relevant literatures was collected to generate a picture of what is known about stress level, and comfort of preterm newborn babies after performing clustered care, the babies who are admitted in NICU for receiving phototherapy, and preterm observation care. Relevant literatures are important sources in providing depth knowledge needed to make changes in the existing practice or to study a selected problem.

Literatures relevant for this study were reviewed and have been organized as follows:

2.1 Research studies related to procedures performed to preterm newborn in Neonatal Intensive Care Unit.

2.2 Research studies related to Stress and comfort level of preterm newborn in NICU.

2.3 Research studies related to effects of clustered care on preterm newborn

2.1 Research studies related to procedures performed to preterm newborn in Neonatal intensive care unit.

A prospective cross-sectional study was conducted to determine the frequency of procedure among 101 neonates in (NICU) in South India. Total number of 6832 invasive and noninvasive procedures and 13 194 disturbances during the study period. The total number of procedures performed was 8.09 ± 5.53 per baby per day and 68.32 ± 64.78 .The most common procedure was heel prick (30%, The HCP were administered a questionnaire to assess their perception of pain for various procedures . Each baby was subjected to 8.09 ± 5.53 (95% CI 6–9; range 1–24) painful procedures every day. The total procedures a baby suffered during 14 days of NICU stay was (68.32 ± 64.78). Preterm babies were disturbed more frequently every day than term babies (18.1 ± 5.8 vs. 15.7 ± 5.2 times per day, $p = 0.035$) and babies ≤32 weeks gestation had more frequent procedures and disturbance everyday as compared with babies >32 weeks gestation procedures per day, $p = 0.029$,and , $p = 0.046$). The study shows the burden of painful procedures on the newborn is still very high. The health personnel are aware of knowledge and practice of better planning in newborn care in NICU. **(Carl Denis Britto 2014).**

An observational, descriptive, exploratory study was conducted in NICU university hospital of Brazil. Twenty preterm infants were selected based on criteria; the preterm infant was filmed for 24 hours using three mini CD Color VR-3256 NTSC DC12V 120mA digital cameras, with three video channels and one audio channel. A Digital Video Surveillance System was used to capture images. The cameras were installed in the following positions at the head, at the feet and on a pedestal of the Preterm infants beside the incubator. The procedures were recorded as starting when the Preterm infant's incubator door was opened and ending when the last procedure was performed and the caregiver closed the incubator door. Thus, the manipulations could occur as individual and grouped manipulations. The type, frequency and duration of each manipulation were measured and recorded in four shifts respectively in morning , afternoon, evening and night the results revels that preterm infants average of 768 manipulations and 1341 procedures. The average duration of the manipulations over the 24-hour period was 2 hours and 26 minutes, most occurring during the morning shift. Individual manipulations accounted for 65.6% of all manipulations, and most manipulations lasted less than a minute. The results of this study show that preterm infants in the NICU underwent an excessive number of manipulations over the 24-hour period evaluated. So it was concluded that preterm infant need to examine the quality of the manipulations performed and the effectiveness of the interventions in the grouping of care, or clustering of care based on the tolerance of the preterm infant**. (Rio De Jeneiro 2014)**

A prospective observational study was conducted in NICU, France, tertiary care Paris Region, to find out the effective strategies to improve pain management in neonates of procedural pain. Data were collected on all neonatal procedures causing pain, stress, or discomfort with the corresponding analgesic therapy. Data was collected for a 6-week period from 430 neonates on all painful and stressful procedures from the first 14 days of admission. The maximum numbers of procedures counted per neonate were high, 613 for all procedures and 364 for only painful procedures .It was listed into 24 common painful and stressful procedures, and analyzed with descriptive and summary statistics, logistic regression analyses were used to explore the possible factors associated with the administration of analgesic therapy. By the treatment of analgesic administration during the time of the procedure the neonates has reduced in stress and discomfort in NICU. Three hundred and four neonates were transferred to level 2

and level 1 units. The study concludes as pain management during procedure was effective in preterm neonates. **(Barker and Rutter, 2013).**

A prospective study was conducted in NICUs at Karolinska Hospital, Sweden**,** to assess the pain on preterm neonates and changes in the physiological parameters .Among 40 newborn infants born after 26 weeks of gestation, who required blood sampling in the NICU. Heart rate and arterial oxygen saturation (Sa2O) data were recorded by a HP monitoring system simultaneously with the NIRS data. Respiration was observed during the procedure. HR and SaO2 average values were averaged at baseline and at 10, 20, 30, 40, 50, and 60 s after the tactile and painful stimuli. No differences occurred between male and female infants in the GA (males 31.4 vs. females 32.7 weeks), during tactile stimulation, no significant changes occurred in the HR (t=142.86±3.32p> 0.05) and SaO2 (t=96.67±2.36,p> 0.05) values. No differences occurred in the HR responses between female and male infants or between neonates receiving painful stimulation on the right vs. the left hand .No differences occurred in SaO2values (t=95.57±2.26 p> 0.05) between male and female neonates or between the two sides of the veni puncture. The study results show that there are no changes in physiological parameters of newborn during painful procedures in NICU. (**Marco Bartocci Lena L, 2013).**

A prospective study was done in Sophia children's hospitals Netherlands .The study group consisted of 151neonates, all the painful procedures were recorded including the number of attempts required and the analgesia therapy used during the first 14 days in neonatal intensive care unit. Pain was assessed on a 10 point scale for all the procedures. The study revealed that each neonate was subjected to a mean of 18 procedures per day. The highest exposure to painful procedures occurs during the first day of admission. Only 35% of neonates were provided with analgesia to relieve pain in NICU **(Simmon, et al., 2012).**

A study to evaluate the long term effects of brain neurodevelopment and pain reactivity among preterm newborn, was conducted in University of British Columbia and Child & Family Research Institute. Canada. The main aim of study was to assess the brain development in relation to stress and painful procedures in the neonatal intensive care unit (NICU). Neonatal pain exposure has been quantified as the number of invasive and/or skin-breaking procedures during hospitalization in the NICU. Very preterm newborns (24-32 weeks) were included in this study respectively, it evidence that repeated procedural pain/stress in very preterm infants

potential risk in alter brain microstructure and function, stress systems, neurodevelopment, and stress-sensitive behaviors. So there is a need for pain management for humanitarian care is widely advocated. Non-pharmacological interventions to help in reduce the infant's stress and brain-protective. It was concluded that Supportive "environmental care" such as reducing noise, light, staff activity, and handling of infant is essential in improving brain structure, activity, and brain development of preterm neonates. **(Ruth Eckstein Grunau, 2012).**

2.2: Research studies related to Stress and comfort of preterm newborn in NICU.

An Experimental study was conducted in Ege University Faculty of Medicine, Department of Pediatrics Turkey. The effectiveness of nesting positions was to assess the pain, stress, comfort and salivary cortisol and melatonin values in nesting positions during the heel lance procedure in premature infants at the NICU. The sample comprised 33 premature neonates with gestational age of 31 to 35 weeks who had been hospitalized in the NICU. Nesting positions were given using linen or towels. The procedure of heel lance was re-corded on camera. The camera recordings were evaluated according to the NIPS and the Comfort scale. Saliva samples were obtained five minutes prior to and 30 min after the heel lance procedure. Salivary Cortisol and Melatonin were measured using the Sal metrics Cortisol Elisa Kit and the Salimetrics Melatonin Elisa Kit.The Results shows the crying time, the mean NIPS score ($t=3.489$, $p<0.000$) the comfort score, NRs for premature neonates who were in the prone position during the procedure were significantly lower than the scores in the supine position. The level of salivary cortisol five minutes prior and 30 min after the heel lance procedure had decreased in the prone position.(**Mehmet Yalaz**, **2017)**

An observational cohort study was conducted in, Neonatal Intensive Care Unit, Taiwan. The study included preterm infants recruited within 24 hours of birth, 14 and 28 days of life. Preterm infant Stress was measured using the Neonatal Infant Stressor Scale (NISS). The average daily exposure to stressors was greatest in the first 14 days of life. Infants with higher NISS scores over the total length of stay were more likely to be immature at birth ($r=-.708$, $p<.001$ in the first 12 hours of life ($r=.483$, $p<.001$) neonates who receive prolonged ventilation during their neonatal stay ($r=.801$, $p<.001$). These relationships were consistent over all three time points. There was no relationship between stressors at all three time points (Karl Pearson's

correlation=−.086, −.191, and −.159) for 1st 14 days. The above findings concluded that neonates who born immature birth have greatest chance of stress in NICU. **(Marcelo Velloso, 2016).**

A randomized controlled trial was done in USA.The study aimed of SSC (Skin-to-skin contact) compared with no SSC in the first 2 to 3 hours post birth showed that the first 2 to 3 hours are a sensitive period for manifestation and control of stress. Among 37 preterm newborn, Skin-to-skin contact diminished infant stress by (70%) in the first 2 to 3 hours. Infants who did not receive SSC continued to have high stress (79%) levels throughout the same period. Stress reduction at birth promoted the SSC infants' abilities to improve the comfort of preterm newborn.**(Neu, Hazel, Robinson, Schmiege, & Laudenslager, 2014).**

A randomized control study was conducted in USA, among 12 preterm infants aged between 28- 34weeks of gestation. They were assessed for the stress response, and comfort of the newborn. The newborn were evaluated using the PIPP during the care giving condition .one with nesting and cling wrap used to current practice in advising sleep positioning for infants , and other with facilitated tucking. For each trail, the preterm newborn received a PIPP score significant difference (p=0.013) existed between the two situations. Nine of the 12 preterm newborn received a lower PIPP score with nesting, and cling wrap cover in. Their rest and sleep were promoted through stress free care by uninterrupted rest. The American Academy of Pediatrics recommends using ‘sleep sack’ or ‘baby sleep bag’ as a type of bedding to keep him warm to promote comfort there by stress of preterm will get reduced.**(Fern R. Hauck 2013).**

An observational study was conducted in Neonatal Intermediate Care Unit, Hospital Universitário do Oeste Paraná, Brazil. This study was to establish whether prone positioning influences stress in premature newborn infants, and the correlation between salivary cortisol concentration on physiological parameters, including heart rate (HR), respiratory rate (RR), and oxygen saturation ($SatO_2$).Sixteen newborn premature infants (56.3%) with a gestational age between 28 and 36 weeks, age between 1 and 33 days, birth weight of 935 to 3,050g newborn who were clinically stable and exhibited normal physiological parameters before sample collection. The samples were collected at least one hour after the last feeding and 40 minutes after any manipulation of the infants. The newborn infants were monitored by means of conventional pulse oxymeter, digital skin thermometers, and observation of the respiratory pattern and behavioral responses by the principal investigator. Prone positioning is only

indicated when healthcare providers detect signs of respiratory distress in newborn infants. There was a significant reduction in the salivary cortisol level, in 81.25% of the sample after prone positioning, found a reduction in the number of stress-indicating behaviors. The median salivary cortisol concentration was lower in the prone position compared to baseline (t=0.13 0.20, p=0.003), as was the median Brazelton sleep score (t=0.6-0.89, p<0.02). The average respiratory rate was lower after the intervention (54.88±7.15 versus 60±7.59; p=0.0004). The results conclude that Prone positioning significantly reduced the salivary cortisol level, respiratory rate, and Brazelton sleep score, suggesting a correlation between prone positioning and reduction of stress in preterm infants. **(Maria Fernanda Cândia 2013).**

An observational study was conducted in Netherland, NICU of the Emma Children's Hospital / Academic Medical Center in the amount of stress and quality of life of preterm newborn. Nineteen preterm babies with gestational age 30 weeks, mean birth weight 1385 gram), were included in this study. Observations took place between the day of birth (day 0) and the fourth day of life. Where by 15 preterm infants were classified as quiet to very quiet and 15 as moving calmly to very agitate. One clinical expert and 9 observers made 30 paired observations, the criterion validity of the Comfort scale (Pearson's r of 0.84). The inter observer reliability (weighted kappa 0.84). The prevalence of stress in NICU was 27% (8 out of 19) which is very likely, taking the clinical judgment into consideration, The problem of stress is increasing as more (40%) of preterm newborn are being ventilated . with an average of 8 days of ventilation. On a short term base stress can result in a prolonged period of ventilation, more chronic lung damage, lower increase of bodyweight and a prolonged period of admittance to the hospital. The findings revels that birth weight and gestational age will influence preterm neonates stress and comfort (**Joke M. Wielenga, 2012).**

2.3: Research studies related to effects of clustered care on preterm newborn.

A prospective observational study was conducted in Royal Women's Hospital in Melbourne, a tertiary level neonatal intensive and special care unit. Thirty-four infants born <30 weeks' gestation were recruited. The physiological stress imposed by standardized neurobehavioral assessments was compared with that during clustered nursing cares. Three standardized neurobehavioral assessments, the General Movements Assessment (GM), the Premie-Neuro Assessment (PN) Hammersmith Neonatal Neurological Examination were

assessed. The pulse oxymeter was positioned inside the incubator/open cot within the camera's view to monitor HR and SpO_2.. Compared with clustered nursing cares HR was lower (mean difference −5.9 bpm; 95% CI −6.5 to 5.3; P<0.001) and oxygen saturation higher (mean difference 2.4%; 95% CI 2.1% to 2.6%; P<0.001) during standardized neurobehavioral assessments. Compared with clustered nursing cares neurobehavioral assessments were also associated with reduced odds of tachycardia (OR 0.44, 95% CI 0.22 to 0.86), HR instability (OR 0.43, 95% CI 0.22 to 0.85) and oxygen desaturation (OR 0.43, 95% CI 0.26 to 0.70).(**Leesa G Allinson., 2017).**

A randomized crossover clinical trial was conducted Tabriz University of Medical Sciences, Tabriz, Iran. Neonatal Intensive Care Unit .Thirty one preterm infants were studied at 32 weeks age by clustered care with three and five procedures, to compare the physiological responses of preterm infants to clustered care. Primary outcomes such as heart rate, respiratory rate and blood oxygen saturation were assessed. The findings showed that the mean of oxygen saturation on before, during and after clustered care with three procedures were respectively 97.52, 97.32, and 97.84 and in clustered care with five procedures were 97.68, 97.94, and 97.65. Heart rate of three procedures was 146.26, 149.90, 149.97 and five procedures were 150.61, 154.77, and 154.65. Respiratory rate of three procedures were respectively 51.68, 48.87, 47.71 and five procedures were 49.10, 48.61, and 49.48. All of these physiological responses were at normal range. The results conclude that significant differences were not found between physiological responses of two groups. (**M Avazeh, N Babaei, 2015)**

A case study was conducted in Cleveland State University, Cleveland, USA on to test Kangaroo Care's effect on pain in one term infant who received clustered painful procedures. Performed on the left side of the body. Clustered painful procedures were tolerated without bradycardia and oxygen desaturation during KC. A two-day-old healthy full term female received two heel sticks and one injection, one right after the other, during one session of KC and showed reduced pain responses (HR, SaO_2, behavioral state, crying time) to each sequential pain experience throughout two heel sticks (10 minutes), injection (30 seconds), and recovery (30 minutes) periods. Each painful procedure increased the infant's heart rate above baseline. The second heel stick increased her heart rate more than the first heel stick, but heart rate was not as greatly increased during the injection (3^{rd} painful procedure). Oxygen saturation did not

decrease with any heel stick or injection and only dropped once (by 5%) during squeezing at the end of the first heel stick, so stability in SaO_2 predominated. Even with three consolidated painful procedures, no bradycardia (heart rate < 120 bpm) nor oxygen desaturation (<88%) occurred. the study conclude that Heart rate increased sequentially with each heel stick, oxygen saturation remained unchanged, sleep predominated, and crying was minimal throughout the procedures. (**Luding –Hoe, 2015)**.

An exploratory prospective observational study was conducted in NICU at a university hospital Brazil. The study performed with 40 Preterm infants weighing less than 1,500 g. The infants were divided into two groups and monitored for 72 hours. One group received the standard minimal handling procedure during the first 12 hours after surfactant therapy, the other group (i.e., the modified group) received minimal handling within 72 hours after surfactant therapy. Infant heart rate (HR),($r=0.48, p<0.002$) oxygen saturation ($r=0.46, P<0.0003$), body temperature ($r=0.67, p<0.0010$, and the adverse events associated with changes to these variables were monitored every 10 minutes. The practice of minimal handling among very low birth weight infants did not alter their physiological stability when performed either 12 or 72 hours after surfactant therapy. The studies conclude that significant differences were not found with between-group regard to the occurrence of the adverse events associated with physiological changes of Preterm neonates. (**Laura A. Cabral 2014).**

Chapter summary:

Literatures related to clustered care, comfort measure, painful procedure on preterm newborn with reduction in stress, maintain physiological parameters, and promote comfort. Studies which included randomized, experimental, observational, prospective study were reviewed deeply for the study. Every research has positive results on clustered care .However most of the study support physiological parameters with clustered care. Literature review helped in selection of tools, developing the study design etc.

CHAPTER-III

MATERIALS AND METHOD

Research design is a blue print for conducting a study. Designing a research involves development of a plan strategy that will guide the data collection and analysis of the data. (Suresh K Sharma., 2007). The present study was to assess the effectiveness of clustered care on physiological Parameters, stress and comfort level among preterm newborn. The methodology of the study constitutes of research design, setting, selection of population and sampling, sampling size determination, criteria for selecting samples, instruments and tools for measuring variables, technique of data collection, method of data analysis, and report of pilot study.

3.1 Research approach:

The research approach used for this study was quantitative evaluative approach.

Research Design:

Quasi- Experimental Design:

The research design used for the study was quasi experimental, multiple time series design with repeated institution of treatment to evaluate the effectiveness of clustered care on physiological parameters, stress and comfort level among preterm newborn. There is no control group in this design.

Preterm newborn Phototherapy group

$O_1 \longrightarrow X_1 \longrightarrow O_2 \longrightarrow X_1 \longrightarrow O_3 \longrightarrow X_1 \longrightarrow O_4$

Preterm care newborn group

$O_1 \longrightarrow X_2 \longrightarrow O_2 \longrightarrow X_2 \longrightarrow O_3 \longrightarrow X_2 \longrightarrow O_4$

Where,

O1- Pre assessment of stress, physiological parameters and comfort level before clustered care in three shifts like morning, afternoon, and night.

X1. Intervention - Administration of clustered care morning, afternoon and in the night for preterm newborn on phototherapy groups for 15-20 minutes.

X2. Administration of clustered care morning, afternoon and in the night for neonates on preterm care groups for 15-20 minutes.

O2- Post assessment of NISS, stress level, physiological parameters, and comfort level on Day I at various time intervals by using pulse oxymeter, NISS, and comfort scale of preterm newborn on phototherapy, and neonates on preterm care.

O3 - Post assessment of NISS, physiological parameters, and comfort level on Day 2 at various time intervals on by using NISS scale, pulse oxymeter, comfort scale of preterm newborn on phototherapy, and neonates on preterm care.

O4 - Post assessment of NISS, physiological parameters, and comfort level on Day 3 at various time intervals on by using NISS scale, pulse oxymeter, comfort scale of preterm newborn on phototherapy, and neonates on preterm care.

3.2 Variables of the study

3.2.1 Independent Variable:

The independent variables in this study is:

- clustered care

3.2.2 Dependent Variable:

The dependent variables of the study are physiological parameters, such as heart rate,respiratory rate,and oxygen saturation,stress and comfort level among preterm newborn .

3.3 Setting of the study:

The study was conducted in Neonatal Intensive Care Unit PSG Hospitals, peelamedu, Coimbatore. PSG Hospitals is a 1135 bedded hospital with multispecialty services in all departments. It is the first teaching hospital in Tamilnadu and third teaching hospital in India to get certified by National Accredited Board for Hospitals and Health Care Providers (NABH). The NICU is a separate unit, with bed strength of 20. Under the experienced and qualified neonatologist and other qualified staffs they provide the quality of care to all the neonates. All the neonatal physician and staff nurses undergo neonatal training and classes to upgrade their knowledge. There are 20 Nurses working in NICU with three shifts, for each shif 6 nurses were assigned.NICU has 3 levels like level 1, 2 and level 3. In level 1, newborn who are admitted for observation care, who are born through LSCS. The criteria for admission to level 2 considering with Preterm neonates who need Phototherapy, Incubator care, Correction of electrolytes imbalance and formula feeding. Level 3 includes sick neonates who require advanced care with ventilator setting, CPAP, respiratory distress syndrome, neonatal seizures etc. The present study was conducted in Level II NICU where neonates are admitted for phototherapy, preterm care for thermoregulation and feeding care.

3.4 Population and Sampling:

The population composed of preterm newborn admitted in NICU of PSG hospitals who were born between 32 -37 weeks of gestational age, and birth weight 1.5 -2.5kgms. The preterm baby either delivered in here (or) referral from outside hospitals also considered. The total number of preterm newborn admitted in NICU was around 1410 from 01-01-2017 to 31-12 2017, and around 35-40 preterm newborn per month were getting admitted for phototherapy care and preterm care. All preterm neonates getting admitted in level 2 NICU for phototherapy, and preterm care were the study subjects.

3.4.1 Sampling Technique and Sample Size:

Non probability Purposive sampling technique was used in this study for selecting study subject. All preterm newborn who met inclusion criteria were selected randomly assigned to preterm newborn on phototherapy and preterm care newborn.

Sample Size and Calculation: Power Analysis Method

$$n = \frac{Z^2 \times N \times SD^2p}{(N-1)\, e^2 + Z^2 \times SD^2p}$$

N = size of population

n = size of sample

e = acceptable error

SDp = standard deviation of a population

Z = standard variation at a given confidence level

$$n = \frac{(1.96)^2 \times 1410 \times (4.6)^2}{(1409) \times (1.5)^2 + (1.96)^2 \times (4.6)^2}$$

$$= \frac{114{,}568.7}{433.50}$$

= 35.6 n=36

Total sample size is 40. Twenty in each group.

3.4.2.1 Sampling Criteria:

Inclusion Criteria:

- Preterm Newborns born with gestational age 32 -37 weeks
- Preterm Newborns admitted in NICU for phototherapy.
- Preterm Newborn admitted in NICU - incubator care, feeding ,and promote weight gain.

Exclusion Criteria:

- Newborn requires either invasive or non invasive ventilation support
- Critically ill preterm newborn
- Congenital anomalies preterm newborn
- Preterm newborn with (RDS-Respiratory distress syndrome)
- Preterm newborn with surgical conditions.

3.5.1: Instrument and tool for data collection: tool consists of four sections.

Section – A : Demographic Profile.

Section – B : Physiological parameters

Section – C : Modified NISS Scale

Section – D : Modified Comfort scale

Section –A: Demographic Profile

Demographic profiles consists of newborn's age, gender, birth weight, gestational age at birth, mode of delivery, duration of hospitalization, and experience of nursing staffs in NICU. (Annexure IV -A)

Section-B: Physiological parameters

It consist of Heart rate,Respiratory rate,and the Oxygen saturation (spo_2%) by using philips pulse oxymeter.The classifications of physiological parameters as follows.(Annexure IVB) **Heart rate was classified according to NICU protocol of PSG Hospitals.**

Heart Rate	**Grade**
110 -120 beats per minute	Mild bradecardia
120-140 beats per minute	Normal heart rate
>140 beats per minute	Mild tachycardia

Respiratory rate was classified according to NICU protocol of PSG Hospitals.

Respiratory Rate	**Grade**
<40 breaths per minute	Mild bradypenia
40-60- breaths per minute	Normal breath rate
>60 breath per minute	Mild tachypenia

Oxgen saturation range according to NICU protocol of PSG Hospitals.

Oxygen saturation at room air (%)	**Interpretation**
>95%	Normal saturation
>90-95%	Mild desaturation
>85-90%	Moderate desaturation
<85%	Severe desaturation

Section C: Modified (NISS-Neonates Infant Stressor Scale):

The Neonatal Infant Stressor scale (NISS) was developed by C.A. New ham T.E. Inter J. et al in 2009 at Parent-Infant Research Institute, Clinical and Health Psychology, Austin Health, Melbourne, Australia. The Neonatal Infant Stressor Scale comprising a list of 44 acute events organized into nursing, peripheral venous access, peripheral arterial access ,central vascular access, ventilation ,nutrition ,medical and surgical procedures, radiology and miscellaneous categories. Out of this 4 components of invasive and noninvasive procedures were formulated in various time intervals which included 2 clusters in the morning (5 –non invasive and 4 –invasive procedures), In afternoon 1 cluster comprising of 5 non invasive procedures and during the night 1 cluster of 6 non invasive procedures were carried out .The stress is classified and graded according to the invasive and painful procedures. It has established inter rated reliability of 0.7. Degree of grading the NISS score from 1-5. 1- Not stressful and 5- Extremely stressful .Scoring and interpretation are given in (Annexure IV- C).

Section D: Modified Comfort scale

The comfort scale was developed by joke M.Wielanga JM -2004. It describes the total eight components. It has established reliability rate positive in each components. It comprises of 8 components organized as alertness, calmness/agitation, respiratory response, physical movement, blood pressure (MAP) base line, heart rate base line, muscle tone and facial tension. Out of this only three

Three components were taken for this study such as alertness, calmness and physical movement. The tool has established inter rater reliability of Alertness (WK) weighted kappa (0.96), calmness (0.86) and Physical movement (0.71), each components minimum score is 1 and maximum score is 5. Details are given in (Annexure IV –D).

Alertness		Calmness / agitation	Physical movement
Deeply asleep	1	Calm-1	No movement-1
Lightly asleep	2	Slightly anxious-2	Occasional, slight movement-2
Drowsy	3	Anxious-3	Frequent, slight movement-3
Fully awake and alert	4	Very anxious-4	Vigorous movement-4
Hyper alert	5	Panicky-5	Vigorous movements including torso and head-5

Instruments for data collection:

Calibrated infanometer was used for checking the daily weight, measuring tape, in centimeters for head circumferences, calibrated Philips pulse oxymeter and cardiac monitor for checking oxygen saturation, heart rate, and respiratory rate. Only same instruments were used throughout the study.

3.5.1 Validity and of the Tool:

Validity of the study tool was determined by obtaining nursing and medical expert's opinion from the different field along with objective of the study. The tools were modified as per the valuable opinion and suggestions of the experts.

Reliability of the Tools:

Reliability refers to precision of the accuracy of measurement of the score. Reliability of the tool was determined using inter rater reliability method. It was computed by the Karl Pearson's reliability was found in.

1. Comfort scale 0.84
2. NISS scale 0.7.

- were assessed before and after the clustered care for both the groups. (Annexure V).

3.5.2 Technique of data collection:

1. Got the permission from hospital (Annexure I)
2. Identified the preterm newborn born between 32 to 37 weeks of gestational age.
3. Objectives, procedure and effect of the study were explained to the parents and their consent was obtained (Annexure III).
4. Existing practice was assessed on stress, physiological parameters and comfort level in both preterm newborn on phototherapy and preterm care.
5. The nurses were taught about clustered care and implemented in each shift. In morning two clusters were formulated which comprised of invasive and non invasive procedures respectively. Single cluster during afternoon and night. Duration of each clustered care was 15-20 minutes.
6. The clustered care was provided for three days and three times a day.
7. Immediately after clustered care Post assessment was done with NISS scale, physiological parameters and comfort scale for both the groups after each time intervals of clustered care.

Intervention: Preterm newborn on phototherapy

- Observation was done on existing practice and it was noticed that the preterm newborn were handled frequently 5 times in the morning, 3 times in the afternoon and 3 times in the night. Since there is mounting evidence that repeated stress especially that occurs during the critical early period of newborn development, has a profound and long lasting effect on several physiological systems. Hence a checklist was prepared for administration of clustered care.
- The clustered care comprised of four or five procedures which were grouped together at various time intervals.
- In the morning 4-5 procedures which included both invasive and non invasive (monitoring vital signs, sponge bath, weighing the newborn, insertion of OG tube/OG feed, collecting blood sample) with 11+12 point stressor scale and the NISS score was 11+12.So it has been formed as two clusters with NISS score cluster 1=11, cluster 2=12.
- In the afternoon single clusters were formed (monitoring vital signs, OG feed/breast feed, nappy changing, eye shield covering, placing under phototherapy) and the NISS score was 11.
- At night also single cluster were formed (monitoring vital signs, monitoring blood glucose, OG feed/breast feed, eye shield covering placing under phototherapy)and the NISS score as 15.
- Depending upon the need and time the clusters were grouped into 4-5, 5-6 procedures. Each day the number of procedures was reduced and the number of handling the newborn also varied from each shifts, the newborns were handled two times instead of 5 times in the morning, single time instead of 3 times in the afternoon and single time instead of 3 times during night.
- Instructed the nurses to perform clustered care with four or five procedures together within 15 to 20 minutes time period. Stress, Physiological parameters and comfort level were evaluated. (Annexure v).

Intervention: Neonates on Preterm care

- Observation was done on existing practice and it was noticed that the preterm care were handled frequently 5 times in the morning, 3 times in the afternoon and 3 times in the night. Since there is mounting evidence that repeated stress especially that occurs during the critical early period of newborn development, has a profound and long lasting effect on several physiological systems. Hence a checklist was prepared for administration of clustered care.
- The clustered care comprised of four or five procedures which were grouped together at various time intervals.
- In the morning 4-5 procedures which included both invasive and non invasive (monitoring vital signs, sponge bath, weighing the newborn, insertion of OG tube/OG feed, collecting blood sample, nesting ,cling wrap) with 11+12 point stressor scale and the NISS score was 11+12.So it has been formed as two clusters with NISS score cluster 1=11, cluster 2=12.
- In the afternoon single cluster were formed (monitoring vital signs, OG feed/breast feed, nappy changing, eye care, attachment of sensor, nesting, cling wrap) and the NISS score was 11.
- At night also single cluster were formed (monitoring vital signs, monitoring blood glucose, Iv line removal, nappy changing, attachment of sensor, nesting, cling wrap) and the NISS score as 15.
- Depending upon the need and time the clusters were grouped into 4-5, 5-6 procedures. Each day the number of procedures was reduced and the number of handling the newborn also varied from each shifts, the newborns were handled two times instead of 5 times in the morning, single time instead of 3 times in the afternoon and single time instead of 3 times during night.
- Instructed the nurses to perform clustered care with four or five procedures together within 15 to 20 minutes time period. Stress, Physiological parameters and comfort level were evaluated. (Annexure v).

3.5.3 Data collection procedure:

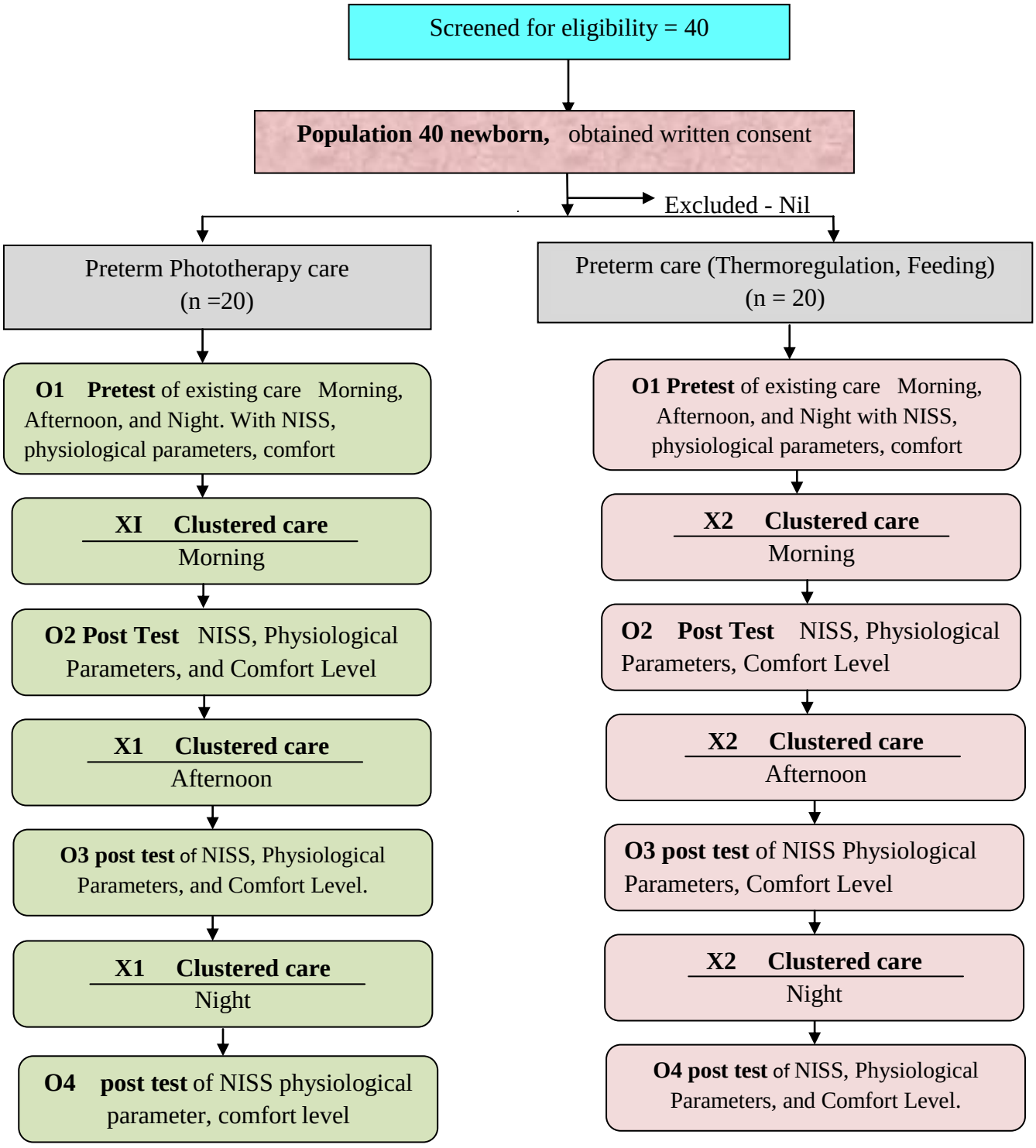

Figure 3.1 Schematic representation of data collection Procedure

3.6 Ethical approval:

The Institutional Human Ethics Committee, PSG Institute of Medical Science and Research reviewed the proposal on its full board meeting and approved the study to conduct. After getting clearance from Institutional Human Ethics Committee data collection was done. (Annexure-II).

3.7 Report of Pilot Study:

Pilot study was conducted to test the practicability of the tool and feasibility of the tool of conducting the study. It was conducted for a period of one week from 30-10-17 to 5-11-17, in Neonatal Intensive Care Unit, PSG Hospitals. Ten preterm newborn who met inclusion criteria, were selected based upon purposive sampling technique. Among these 5 as preterm newborn care and another 5 as phototherapy newborn. Clustered care was initiated to improve the physiological parameters, the comfort and reducing the stress level of preterm newborn .The post assessment was conducted for 3 times a day. Pilot study showed that the tool was reliable and result's indicates that there was significant difference in reducing stress level and promoting comfort among both the groups.

3.7.1 Changes brought after pilot study:

After the pilot study modifications were done in pre assessment for one day for three times, and before clustered care. Post assessment after the clustered care was three days and three times for all the parameters for both groups.

3.8 Data Analysis plan:

Both descriptive and inferential statistics will be used to analyze data.

The demographic data will be presented in frequency and percentage of NISS scores physiological parameters and comfort are measured as inferential statistics.

- Mean and standard deviation will be used to describe NISS scores physiological parameters, and comfort level with before and after clustered care for both the groups.

- Paired ‘t’ test will be applied to test the effectiveness of clustered care on physiological parameters, stress and comfort level of preterm newborn on phototherapy, and preterm newborn care before and after the clustered care.

- Interquaterile Z Wilcoxon signed rank test will be used to compare the pre post assessment of median range of comfort score of preterm newborn on phototherapy, and preterm care.

- Chi square test will be computed to determine the association between pretest of clustered care with selected demographic variables of comfort level of preterm newborn on phototherapy, and preterm care.

Chapter Summary:

This chapter discussed the materials and methodology used for the present study. The methods used in this study is Quasi experimental, time series design and Purposive sampling technique. This chapter also dealt with the variables, settings, instruments, tools for data collection and the data analysis plan. Next chapter will be dealing on data analysis and interpretation.

CHAPTER IV

DATA ANALYSIS AND INTERPRETATION

Analysis is a process of organizing the data in such a way that research question can be answered .It includes the synthesis of research data and the testing of research hypothesis using those data. Interpretation is the process of making sum of the result and of examining implication of the finding with in the broader context. **(Polit and beck, 2008)**

This chapter deals with the analysis and interpretation of data collected from preterm newborn on phototherapy, preterm care newborn admitted in NICU. To assess the effectiveness of clustered care on physiological parameters, stress and comfort level among both the groups. The data was complied, analyzed and then tested for their significance with SPSS IBM version 24.

The chapter is organized under the following sections:

Section I - Analysis of preterm newborn on phototherapy

4.1 Frequency and percentage distribution of Preterm newborn on Phototherapy and Preterm care according to demographic profiles.

4.1.2 Description of existing practices of care and clusters of Preterm newborn on phototherapy.

4.1.3 Comparison of Pre and post test NISS scores of Preterm newborn on phototherapy.

4.1.4 Comparison of pre and post test score of physiological parameters of Preterm newborn on phototherapy.

4.1.5 Comparison of pre and post test comfort scores of Preterm newborn on phototherapy.

Section II - Analysis of preterm newborn on preterm care

4.2 1. Description of existing practices of care and clusters of neonates on preterm care.

4.2.2 Comparison of pre and post test of NISS scores of neonates on preterm care.

4.2.3 Comparison of pre and post test score of physiological parameters of neonates on preterm care.

4.2.4 Comparison of pre and post test comfort score of neonates on preterm care.

4.1 Demographic Data of the preterm newborn on Phototherapy and Neonates on Preterm care.

Table 4:1 Frequency and percentage of demographic factors of preterm newborn on phototherapy and Neonates on preterm care.

n=40

S.No	Demographic variables	Phototherapy group		Preterm group	
		f	%	f	%
1	**Age of the Newborn**				
	0-3 days	12	60	13	65
	4-7 days	8	40	7	35
2.	**Gender of the newborn**				
	Male	8	40	9	45
	Female	12	60	11	55
3	**Birth weight of the newborn**				
	1.5-2 kg	9	45	13	65
	2.1-2.5 kg	11	55	7	35
4	**Gestation weeks of the mother**				
	32-34	11	55	13	65
	35-37	9	45	7	35
5.	**Mode of delivery**				
	Normal vaginal delivery	11	55	10	50
	Lower segment caesarian section	9	45	10	50
6.	**Duration of the hospitalization**				
	0-3days	3	15	6	30
	4-7 days	17	85	14	70
7.	**Experience of the nursing staff in NICU**				
	6 months -1 year	6	30	3	15
	1.1 - 2 years	8	40	3	15
	2.1 - 3 years	3	15	4	20
	> 3 years	3	15	10	50

Table 4.1 shows that most of the babies 12 (60%) and 13 (65%) preterm newborn were aged 0-3 days in phototherapy and preterm care. Only 8(40) and 7(35) were 4-7 days of birth in both the group. Forty preterm 8 (40%) were male in phototherapy and 9 (45%), were in preterm group respectively. Among 40 preterm 9(45%) of preterm newborn on phototherapy and 13 (65%) preterm neonates birth weight was 1.5-2kgs respectively. With regard to the gestational age more than half of the preterm newborn 11(55%) in the phototherapy group and 13(65%) were in 32-34 weeks of gestation in preterm care newborn. Majority of 17 (85%) Preterm newborn on phototherapy and 14 (70%) preterm care were hospitalized for 4-7 days. Regarding the experience of the NICU Nurses the minimum experience was 6 months-1 year (30%) in phototherapy group half of the nurses 10(50%) who were caring the preterm care group had more than 3 years of experience.

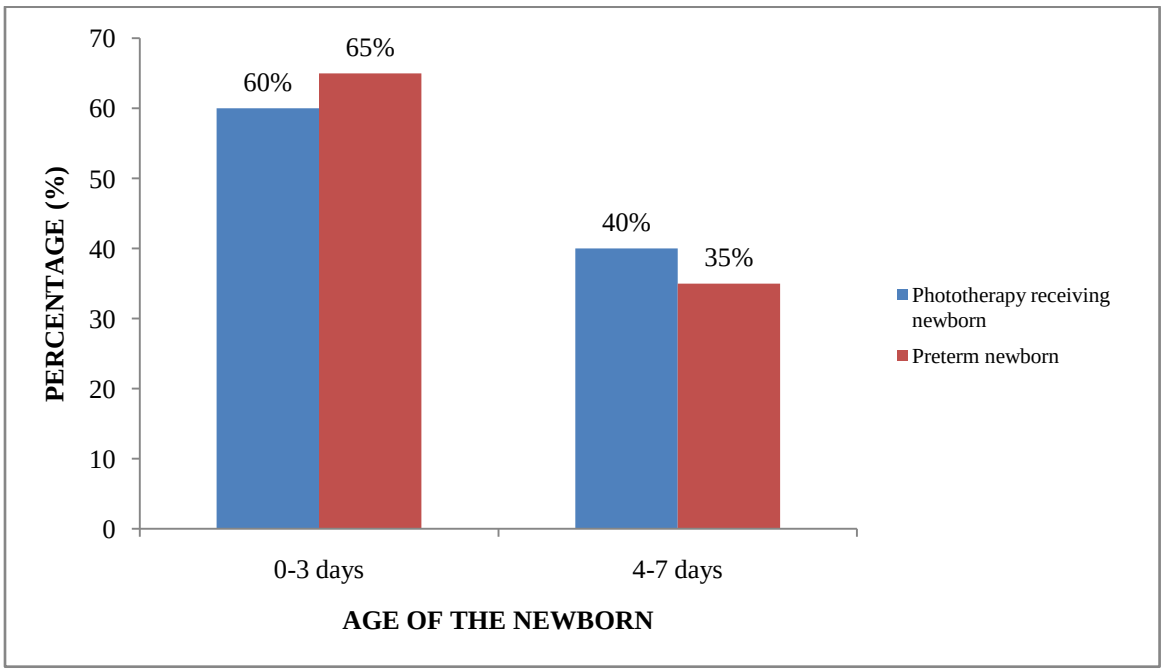

Figure 4.1: Bar diagram showing the percentage distribution of age of the preterm newborn on phototherapy and preterm care newborn

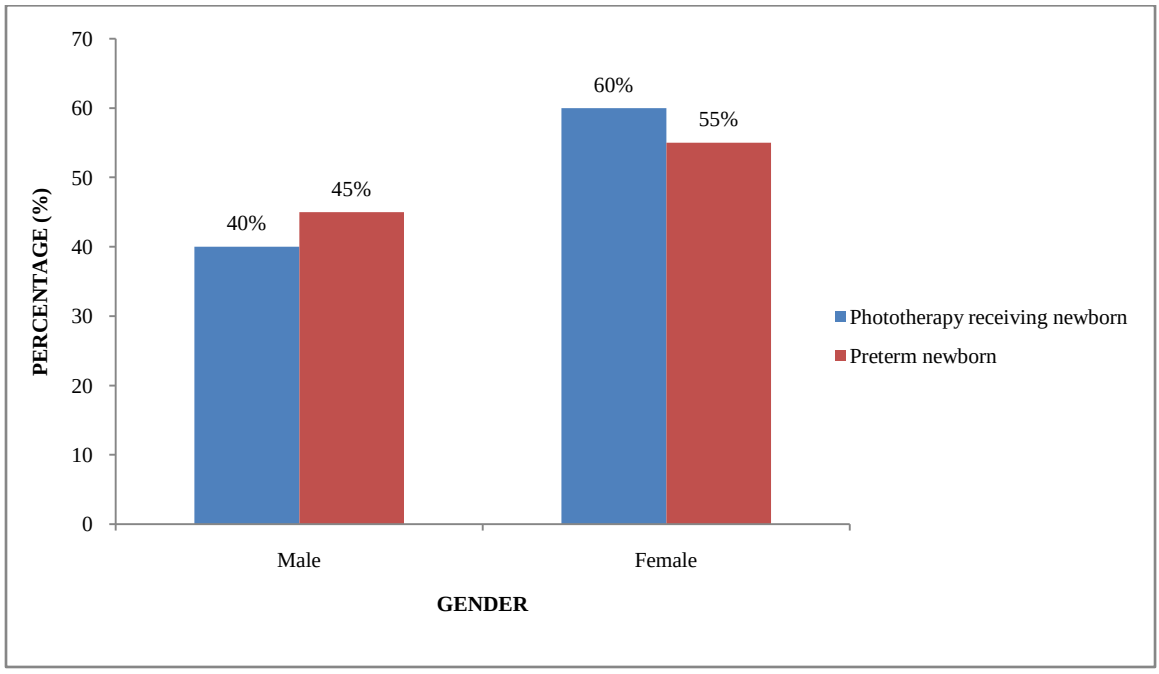

Figure 4.2 Bar diagram showing the percentage distribution of the gender in preterm newborn on phototherapy and preterm care newborn

Table 4.1.2 :Description of existing practices of care and clusters of preterm newborn on phototherapy

S.No.	Duration	Before Cluster Care				After Cluster Care			
		Time Interval	Procedure performed	NISS Score	Frequency of Handling	Time Interval	Procedure performed	NISS Score	Frequency of Handling
1	Morning	7.00 am	Sponge bath	2	5 times	7 - 7.15am	Sponge bath	2	Once
		7. 10 am	Monitoring vital signs	2			Monitoring Vital signs	2	
		7.15 am	Weighing the newborn	3			weighing the baby	3	
		8 .10 am	Attachment of sensor	2			Attachment of sensor	2	
		8.20 am	Placing under phototherapy	2			Placing under phototherapy	2	
		8.30 am	OG insertion/OG feeding/breast feed.	2			**Total score**	**11**	
		8.40 am	Changing the nappy	3		9.30 – 9.50 am	I.V Insertion	4	Once
		10.00am	Iv insertion	4			Blood Collection	2	
		11.00am	Collecting blood sample	3			OG insertion	3	
							Nappy changing	3	
			Total score	**23**			**Total score**	**12**	
2	Afternoon	2.00 pm	Monitoring vital signs	2	3 times	2 -2.20 pm	Monitoring Vital signs	2	Once
		2.20 pm	Nappy changing	3			Nappy changing	3	
		2.25 pm	Eye shield covering	2			Eye shield covering	2	
		2.30 pm	Attachment of sensor	2			Attachment of sensor	2	
		2.50 pm	Placing under phototherapy	2			Placing under phototherapy	2	
			Total score	**11**			**Total score**	**11**	
3	Night	7.30 pm	Monitoring vital signs	2	3 times	8-8.20 pm	Monitoring Vital signs	2	Once
		8.00 pm	Changing the nappy	3			Monitoring Blood glucose	4	
		8.05 pm	Eye shield covering	2			Nappy changing	2	
		8.10 pm	Attachment of sensor	2			Attachment of sensor	2	
		8.15 pm	Placing under phototherapy	2			Eye shield covering	2	
		9.00 pm	Monitoring blood glucose	4			Placing under phototherapy	3	
			Total score	**15**			**Total score**	**15**	

Note: not stressful—intermittent NG feed, bottle feed, cup feed, breast feed, continuous nasogastric feeding.

NISS SCORE: A little stressful -2 , moderately stressful -3, very stressful -4, extremely stressful -5.

As shown in table 4.1.2 NISS score was described before and after clustered care of preterm new born on phototherapy with the existing practice. The preterm new born were handled frequently in the morning for invasive and non invasive procedures (5 times). In order to reduce the frequent handling of preterm newborn on phototherapy the cluster was grouped twice in the morning with group of 5 procedures in the first cluster and 4 procedures in the second cluster. The total NISS score was 23 based on each procedure during the existing practice and in the 2 clusters was formed and the NISS score was 11 and 12 respectively.

In the afternoon the existing practice showed that the preterm newborn on phototherapy were handled frequently with the NISS score of 11 where as in cluster care the procedures were grouped into a single cluster, the NISS score was 11.

Similarly in the night the preterm newborn on phototherapy were handled frequently with the NISS score of 15 with 6 procedures. In the cluster care handling was minimized as the procedures were grouped into a single cluster with score of 15.

Table 4.1.3: Comparison of pre and post test NISS scores of preterm newborn on phototherapy

Null hypothesis (Ho_1) There will be no significant difference in pre and post test NISS scores on clustered care among preterm newborn on phototherapy

n=20

No of days		Duration	Mean ± SD NISS score	"t" value	Table value	σ^2 standard error	95% confidence Interval	P value
Day 1	Morning	Pretest	16.8±1.77	7.28	2.09	0.494	2.37- 4.43	0.001**
		Post test	13.5 ±1.10					
	Afternoon	Pretest	10.7±0.923	0.325		0.460	1.11 - 0.81	0.748
		Post test	10.9 ±1.53					
	Night	Pretest	12.5 ±2.02	1.64		0.578	0.26 - 2.16	0.117
		Post test	11.5 ±1.70					
Day 2	Morning	Pretest	16.8±1.77	8.18	2.09	0.629	3.83 - 6.47	0.001**
		Post test	11.75 ±2.63					
	Afternoon	Pretest	10.7±0.923	2.99		0.401	0.36 - 2.04	0.007**
		Post test	9.5 ±1.5					
	Night	Pretest	12.5 ±2.02	5.01		0.439	1.28 - 3.12	0.001**
		Post test	10.25 ±1.58					
Day 3	Morning	Pretest	16.8±1.77	9.21	2.09	0.732	5.22 - 8.28	0.001**
		Post test	10.15 ±1.41					
	Afternoon	Pretest	10.7±0.923	5.17		0.357	1.10 - 2.60	0.001**
		Post test	8.85 ±1.38					
	Night	Pretest	12.5 ±2.02	5.66		0.609	2.18 - 4.72	0.001**
		Post test	9 ±1.46					

Note: * significant p<0.05, ** significant p<0.001.

As shown in table 4.1.3 The NISS score before clustered care and after initiation of clustered care the NISS score according to the number of procedures performed in the morning were compared. The mean NISS score in the morning shift was16.8±1.77 before clustered care. On first day after clustered care the mean NISS scores was 13.5 ±1.10 and was statistically significant (t=7.28, p<0.001), at 95% CI (2.37- 4 .43).

Similarly the mean of the afternoon pretest NISS score before clustered care was 10.7 ±0.923 and after clustered care with 5 procedures to the mean NISS post test score was 10.9 ±1.53. Which was not statistically significant p<0.748) .There was no statistical difference in the mean NISS scores the first day night before and after clustered care.

On the second day the mean of NISS score in the morning 11.75±2.63, (t=8.18, p<0.001at 95% CI (3.83 - 6.47).As compared to pretest NISS score based on the number of procedures 5 clustered there was a further reduction of NISS score. Where as in afternoon mean NISS score 9.5±1.5 and during the night 10.25±1.58 at 95%CI (5.22- 8.28) p<0.001which is also statistically significant.

There was a significant reduction in the mean NISS score on third day with 4 and five procedures clusters in the morning (10.15 ±1.41), afternoon 8.85±1.38 and during the night 9±1.46 ,p<0.001).

These findings reveals the NISS score on pretest was high and after formation of 2 clusters in the morning and 1 cluster in the afternoon and night .According the number of procedures the stress reduced.

Hence it can concluded that clustered care is effective in reducing the stress .Hence the null hypothesis is rejected and research hypothesis is accepted.

Table 4.1.4 Comparison of pre and post test score of physiological parameters of preterm newborn on phototherapy

Null hypothesis (Ho2) There will be no significant difference in pre and post test of physiological parameter on clustered care among preterm newborn on phototherapy

n =20

S.No	No. of days	Physiological parameters		Mean±SD	Calculated 't' Value	Table	P value
	Pre test			144.76±4.57			
1	Post test 1	HR	Day 1	144.09±4.57	1.20	2.09	0.244
			Day 2	143.39±3.18	1.87		0.075
			Day 3	142.86±3.32	2.45		0.023**
	Pretest			45.72±2.3			
2	Post test 2	RR	Day 1	45.24±2.08	1.20	2.09	0.243
			Day 2	44.16±1.83	3.18		0.004**
			Day 3	42.99±1.76	6.02		0.001**
	Pretest			96.67±2.36			
3	Post test 3	Spo_2	Day 1	98.13±1.07	3.69	2.09	0.001**
			Day 2	98.24±0.99	3.18		0.004**
			Day 3	99.08±1.05	4.19		0.001**

Note:* significant difference p< 0.05, ** significant difference p< 0.001

HR: Heart Rate, RR; Respiratory Rate, spo_2: Oxygen Saturation

The physiological parameter Heart rate, Respiratory rate and Oxygen saturation was compared within groups before and after clustered care, in the morning, afternoon and night from day 1 – day-3.The data was analysed by paired "t" test. The mean HR, RR, and Spo_2 (%) of all three shifts were complied as day 1, day 2 and day 3. To compare the differences in these physiological parameters the null hypothesis was formed as, Null hypothesis (Ho_2) There will be no significant difference in pre and post test physiological parameters on clustered care among preterm newborn on phototherapy.

As shown in table 4.1.4 the mean HR before clustered care was (144.76±4.57). On the Ist day after clustered care the mean HR was (144.09±4.57). (t= 1.20, p< 0.244). Which is not statistically significant.

On the 2nd day also there was a slight reduction in the mean HR as compared to pretest. However it was also not statistically significant (p= 0.075).HR (143.39±3.18.)

On third day after clustered care there was a significant reduction in the mean HR(142.86±3.32) as compared to the pretest HR which was statistically significant (t=2.45, p<0.023) which shows that there was a significant reduction of heart rate on third day on physiological parameter of preterm newborn on phototherapy. However the heart rate was within normal limits.

Similarly the mean RR before clustered care was (45.24±2.08). On first day after clustered care the mean RR was (45.24. ±2.08), (t=1.20p= 0.243). Which is not statistically significant.

On second day also there was a slight reduction in the mean RR as compared to pretest and it was statistically significant (t=3.18, p<0.004).RR (44.16±1.83).

On third day after clustered care there was significant reduction in RR (42.99±1.76) as compared to pretest RR which was statistically significant (t=6.02p<0.001). These findings reveals clustered care was effective in reducing the respiratory rate and, thereby reducing the stress.

Regarding oxygen saturation before clustered care was 96.67±2.36. On first day after clustered care the mean Spo2 was (98.13±1.07), (t= 3.69 p<0.001) which is statistically significant.

On second day the mean oxygen saturation was increased compared to pretest was (98.24±0.99). (t=3.18, p<0.004).which is statistically significant.

On third day after clustered care there was significant improvement in mean oxygen saturation was (99.08±1.05), (t= 4.19 p<0.001).which is also statistically significant. These findings reveals clustered care was effective in improving the oxygen saturation on all 3days.

It is evident from these findings that clustered care was effective in maintaining physiological parameters of preterm newborn who receives phototherapy.

The overall mean of post test score of preterm newborn on phototherapy group, In terms of physiological parameter was highly significant on third day in heart rate($t=2.45 p<0.023$),and in respiratory rate significant difference found in second day($t=3.18$, $p<0.004$),and in third day($t=6.02. p<0.001$).however in oxygen saturation post test score was found highly significant on all three days (D1-$t= 3.69$ $p<0.001$), (D2- $t=3.18$, $p<0.004$),and (D-3 $t= 4.19$ $p<0.001$). From these results it can be infered the clustered care did not cause stress in terms of physiological parameters and the preterm of 32-37 weeks of gestation were able to tolerate clustered care. Hence the null hypothesis was rejected and research hypothesis was accepted.

Table: 4.1.5 Comparison of pre and post median (IQR) comfort score of preterm newborn on phototherapy

n=20

Comfort Score	No. of Days		Z Wilcoxon Sign Rank Test			
				Morning	Afternoon	Night
1. Alertness	**Pre test**		Median(IQR)	2(2-3)	2(2-4)	2(2-2)
	Day – 1	**Post test**	Median Test score CI(95%) P -Value	2 (2-2) -3.187 0.000-.139 0.008	2(2-2) -3.153 0.000-.139 0.005*	2(1-2) -3.127 0.000-139 0.001**
	Pre test		Median (IQR)	2(2-3)	3(2-4)	2(2-2)
	Day – 2	**Post test**	Median Test score CI(95%) P -Value	2(1-2) -3.402 0.000-.139 0.005*	1(1-1) -3.919 0.000-.139 0.001**	1(1-1) -3.753 .000-.139 0.001**
	Pre test		Median (IQR)	2(2-3)	3(2-4)	2(2-2)
	Day – 3	**Post test**	Median Test score CI(95%) P -Value	1(1-2) -3.861 0.000-.139 0.001**	1(1-1) -3.983 0.000-139 0.001**	1(1-1) -3.943 0.000-.139 0.001**
2. Calmness	**Pre test**		Median (IQR)	3(3-4)	3(2-3)	2(2-3)
	Day-1	**Post test**	Median Test score CI (95%) P –Value	2(1-2) -3.387 0.000-.139 0.001**	2(1-2) -3.387 0.00-.139 0.001**	2(2-2) -3.153 0.00-.231 .052
	Pre test		Median(IQR)	3(3-4)	3(2-3)	2(2-3)
	Day – 2	**Post test**	Median Test score CI(95%) P –Value	2(1-2) -3.465 0.00-.139 0.001**	2(1-2) -3.456 0.000-.139 0.001**	2(1-2) -3.643 0.000-.146 0.011
	Pre test		Median (IQR)	3(3-4)	3(2-3)	2(2-3)
	Day – 3	**Post test**	Median Test score CI(95%) P –Value	1(1-2) -3.867 0.000-.139 0.001**	1(1-1) -3.765 0.000-.139 0.001**	1(1-1) -3.934 0.000-.139 0.001**
3. Physical Movement	**Pre test**		Median (IQR)	3(2-3)	2(2-3)	2(2-3)
	Day – 1	**Post test**	Median Test score CI(95%) P –Value	2 (2-2) -3.787 0.000-.146 0.004	2 (2-2) -3.787 0.000-.139 .011	2(1-2) -3.353 .025-.375 .014
		Pre test	Median (IQR)	3(2-3)	2(2-3)	2(2-3)
	Day – 2	**Post test**	Median Test score CI(95%) P –Value	2(1-2) -3.898 0.000-.139 0.001**	2(1-2) 3.898 0.000-.139 0.003	2(1-2) -3.943 0.000-.139 0.002
	Pre test		Median (IQR)	3(2-3)	2(2-3)	2(2-3)
	Day – 3	**Post test**	Median CI(95%) P –Value	1(1-2) -3.996 0.000-.139 0.001**	1(1-1) -3.943 0.000-.139 0.001**	1(1-1) -3.894 0.000-.139 0.001**

Note: * 0.005, p** 0.001

Alertness: 1-Deeply asleep, 2-Lightly asleep, 3- Drowsy, 4- Fully awake and alert, 5- Hyper alert.

Calmness/agitation: 1- Calm, 2- Slightly anxious, 3-Anxious, 4- Very anxious, 5- Panicky.

Physical movement: 1- No movement, 2- Occasional, slight movement, 3-Frequent slight movement, 4-Vigorous, Movement, 5-Vigorous movements including torso and head.

In this section the comfort level of the preterm newborn on phototherapy was compared before and after clustered care.

Wilcoxon sign rank test was used to compare the median comfort scores within the group from day 1 to day 3 at morning, afternoon and night shift according to the number of clusters. To test the comfort level within the group at various time intervals the null hypothesis was formed.

Ho3 Null hypothesis there will be no significant difference in pre and post test of comfort score on clustered care among preterm newborn on phototherapy.

Table 4.1.5 shows the median comfort scores before and after clustered care from day 1 to day 3.

As shown in table 4.1.5 before clustered care the preterm newborn on phototherapy were in slightly asleep state in the morning 2(2-3),afternoon 2(2-4)and night 2(2-2) respectively.

Alertness:

On the first day after clustered care with 4-5 procedures in the morning the preterm newborn were in slightly asleep state 2(2-2) as compared to pretest and was found to be statistically significant CI(0.000-.139p<0.008).In the afternoon also they remained in slightly asleep state 2(2-2).which was also statistically significant CI (-3.153,p<0.005).In the night after clustered care the preterm newborn was in slightly asleep to deeply asleep which was also statistically significant (p<0.001).

There was a significant difference in the level of alertness in the second day as compared to the pretest on day 1,the level of alertness ranged from slightly asleep 2 (1-2) in the morning and deeply asleep state in the afternoon 1(1-1) and night 1(1-1) which is statistically significant (p<0.001).

On third day the preterm newborn constantly remained in the state of deeply asleep state, morning 1 (1-2) afternoon1 (1-1) and night1 (1-1) and statistically significant at all time intervals p<0.001).

Calmness:

The level of calmness before clustered care the phototherapy newborn were in anxious state 3 (3-4) in the morning, remain same state in afternoon and slightly anxious state 2(2-3) in the night.

On 1st day of clustered care after 2 clusters (4- 5 procedures) in the morning the preterm newborn were in slightly anxious state 2(2-2) as compared to pretest and was found to be statistically significant CI (0.000-.139p<0.008), in the afternoon 2(1-2) and night also, remained slightly anxious state. 2(2-2), CI (0.000-.139,p<.052).

Similarly on second day the preterm newborn were in slightly anxious in morning 2(12).when compared to pretest median score the calmness state was same in afternoon 2(1-2).This was also sustained in night 2(1-2) p<0.011), which is statistically significant at all times.

On third day also the preterm newborn constantly were in calm state in morning 1(1-2) afternoon1 (1-1) and night1 (1-1) (CI (0.000-.139, p<0.001).

Physical movement:

In terms of physical movement before clustered care preterm newborn in were in frequent slight movement state 3(2-3) in the morning, in afternoon they were in state of occasional slight movement 2(2-2) and it was remain same state in night 2(2-2) CI (0.000-.139,p<0.001).

Physical movement on 1st day after clustered care in the morning the preterm newborn were in frequent slight movement 3(2-3)as compared to pretest and was found to be statistically significant CI(0.000-.139p<0.001) in afternoon 2(1-2) and night 2(2-2),CI(0.000-.139,p<.002). Which was also statistically significant.

Similarly on second day in the physical movement state the babies were in occasional slight movement 2(12) in the morning .when compared to pretest median score the physical movement state was constant in afternoon 2(1-2) and night 2(1-2),(CI 0.000-.146,p<0.002).

On third day of clustered care as compared to a pretest state frequent slight movement the babies were in no movement state in the morning 1(1-2) afternoon 1 (1-1) and night 1 (1-1) (CI (0.000-.139, p<0.001). Which was also statistically significant in all three time intervals.

From these findings it can be inferred that clustered care altered the level of comfort and improved the level alertness from fully awake state to deeply asleep state, calmness state of anxious to calm state and Physical movement frequent slight movement to no movement state. Hence it can concluded that clustered care was effective in improving the comfort level of preterm newborn who receive phototherapy .Hence the null hypothesis is rejected and research hypothesis is accepted.

Table 4.2.1 Description of existing practices of care and clusters of neonates on preterm care.

S.No.	Duration	Before Cluster Care				After Cluster Care			
		Time Interval	Procedure performed	NISS Score	Frequency of Handling	Time Interval	Procedure performed	NISS Score	Frequency of Handling
1	Morning	7.00 am	Sponge bath	2	5 times	7 - 7.15am	Sponge bath	2	Once
		7.05 am	Monitoring Vital signs	2			Monitoring Vital signs	2	
		7.10 am	Weighing the baby	3			weighing the baby	3	
		7.50 am	Attachment of sensor	2			Attachment of sensor	2	
		7.55 am	Nesting ,cling wrap	3			Nesting, cling wrap	2	
		8.00 am	OG insertion/OG feeding/breast feed	2			**Total score**	**11**	Once
		8.20am	Nappy changing	3		9.30 – 9 .50 am	I.V Insertion	4	
							Blood Collection	2	
		8 50 am	I.v insertion	4			OG insertion	3	
		9.00 am	Blood collection	2			Nappy changing	3	
			Total score	**23**			**Total score**	**12**	
2	Afternoon	2 .00 pm	Monitoring vital signs	2	3 times	2 -2.20 pm	Monitoring Vital signs	2	Once
		2.10 pm	Changing the nappy	3			Eye care	2	
		2.15 pm	Eye care	2			Nappy changing	3	
		2.20 pm	Attachment of sensor	2			Attachment of sensor	2	
		2.25 pm	Nesting ,cling wrap	2			Nesting, cling wrap	2	
			Total score	**11**			**Total score**	**11**	
3	Night	7.30 pm	Monitoring vital signs	2	3 times	8-8.20 pm	Monitoring Vital signs	2	Once
		8 .15 pm	Changing the nappy	3			Monitoring Blood glucose	4	
		8.20 pm	Attachment of sensor	2			Iv line removal	2	
		8.25 pm	Nesting, cling wrap	2			Nappy changing	2	
		8 .30 pm	Monitoring blood glucose	2			Attachment of sensor	2	
		8. 45 pm	Iv removal	4			Nesting, cling wrap	3	
			Total score	**15**			**Total score**	**15**	

Note: Not stressful—Intermittent NG feed, Bottle feed, Cup feed, Breast feed, Continuous nasogastric feeding.

NISS score: A little stressful -2, moderately stressful -3, very stressful -4, and extremely stressful 5.

As shown in table 4.2.1 NISS score was assessed before and after clustered care for preterm care with the existing practice. The preterm new born were handled frequently in the morning for invasive and non invasive procedures (5 times). In order to reduce the frequent handling the cluster was grouped twice in the morning with group of 5 procedures in the first cluster and 4 procedures in the second cluster. The total NISS score was 23 based on each procedure during the existing practice and in the 2 clusters was formed and the NISS score was 11 and 12 respectively.

In the afternoon the existing practice showed that the preterm newborn were handled frequently during the preterm care with the NISS score of 11 where as in cluster care the procedures were grouped into a single cluster, the NISS score was 11.

Similarly in the night the preterm newborn were handled frequently with the NISS score of 15 with 6 procedures. In the cluster care handling was minimized as the procedures were grouped into a single cluster with score of 15.

Table: 4.2.2 Comparison of pre and post assessment of NISS scores of neonates on preterm care.

Null hypothesis (Ho_4) there will not be significant difference in pre and post test of NISS score on clustered care among preterm care

n=20

No of days		Duration	Mean ± SD NISS SCORE	"t" Value	Table value	σ^2 standard error	95% confidence Interval	P value
Day 1	Morning	Pretest	17.25±2.61	3.176*	2.09	0.519	0.56- 2.74	0.005*
		Post test	15.6±1.67					
	Afternoon	Pretest	11.4 ± 0.94	2.179		0.275	0.02-1.18	0.042*
		Post test	10.8±1.51					
	Night	Pretest	13 ± 1.52	0.256		0.390	0.092-0.72	0.008
		Post test	13.1±1.41					
Day 2	Morning	Pretest	17.25± 2.61	3.924	2.09	0.647	0.20-3.90	0.009*
		Post test	14.7±1.63					
	Afternoon	Pretest	11.4±0.94	2.706		0.296	0.18-1.42	0.014*
		Post test	10.6±1.57					
	Night	Pretest	13±1.52	1.872		0.481	-0.11-1.91	0.076
		Post test	12.5±0.76					
Day 3	Morning	Pretest	17.25 2.61	5.728	2.09	0.663	2.41-5.19	0.001**
		Post test	13.45 ± 1.57					
	Afternoon	Pretest	11.4 ± 0.94	5.615		0.276	0.97- 2.13	0.001**
		Post test	9.85±0.67					
	Night	Pretest	13±1.52	5.29s		0.406	1.30-3.00	0.001**
		Post test	10.85±0.93					

Note: * significant $p<0.05$, ** significant $p<0.001$.

As shown in table 4.2.2 after initiation of clustered care the NISS score according to the number of procedures performed in the morning were scored. The mean NISS score in the morning shift was17.25±2.61 before clustered care. On first day after clustered care the mean NISS scores (2 clusters) was 15.6 ±1.67 and was statistically significant (t=3.176, p<0.005), at 95% CI (0.56-2.74).

Similarly the mean of the afternoon pretest NISS score before clustered care was 11.4 ±0.94 and after 1 clustered care with 5 procedures to the mean NISS post test score was 10.8 ±1.51. Which was not statistically significant p= 0.042) .There was no statistical difference in the mean NISS scores the first day night before and after clustered care.

On the second day the mean of NISS score in the morning 10.75±1.57, (t=3.924, p<0.009 at 95% CI (0.20-3.90).As compared to pretest NISS score based on the number of procedures (5) clustered there was a further reduction of NISS score, where as in afternoon mean NISS score was 10.6±1.57 and during the night 12.5±0.76 at 95% CI (-0.11-1.91, p= 0.076 which is not statistically significant.

On third day the NISS score for 4 and five procedures (2)clusters was in the morning (13.45 ±1.57) afternoon 9.85±0.67 and during the night 10.85±0.93 which is also statistically significant p<0.001).

Hence it can concluded that clustered care is effective in reducing the stress. Hence the null hypothesis is rejected and research hypothesis is accepted.

Table: 4.2.3: Comparison of pre and post test score of physiological parameters of neonates on preterm care.

Null hypothesis (Ho5) there will be significant difference in pre and post test of physiological parameter on clustered care among preterm care

n=20

S.No	No of days	Physiological parameters		Mean± SD	Calculated 't' value	Table Value	P value
pre test				147.55±8.40			
1	HR	Post test	Day 1	146.11±5.41	1.360	2.093	0.189
			Day 2	145.86±4.69	1.210		0.240
			Day 3	144.82±4.29	1.855		0.079
	Pretest			49.79±5.98			
2	RR	Post test	Day 1	47.60±4.92	5.34	2.093	0.001**
			Day 2	46.07±4.69	6.04		0.001**
			Day 3	44.41±4.50	8.81		0.001**
	Pretest			95.43±2.34			
3	SPO2	Post test	Day 1	97.93±0.849	5.62	2.093	0.001**
			Day 2	98.54±0.729	5.69		0.001**
			Day 3	99.06±0.80	6.57		0.001**

Note: * –significant $p < 0.05$ ** –significant $p < 0.001$

HR: Heart Rate, RR; Respiratory Rate, $spo_{2:}$ Oxygen Saturation

The physiological parameter Heart rate, Respiratory rate and Oxygen saturation was compared within groups before and after clustered care, in the morning, afternoon and night from day 1 – day-3. The data was analyzed by paired 't' test. The mean HR, RR, and Spo_2 (%) of all three shifts were complied as day 1, day 2 and day 3. To compare the differences in these physiological parameters the Ho_5 has formed as,

Null hypothesis (Ho_5) There will be no significant difference in pre and post test NISS scores on clustered care among preterm care.

As shown in table 4.2.3 the mean HR before clustered care was (147.55±8.40). On the 1st day after clustered care the mean HR was (146.11±5.41). (t= 1.360, p<= 0.189). Which is not statistically significant.

On the 2nd day also there was a slight reduction in the mean HR as compared to pretest. However it was also not statistically significant HR (143.39±3.18), (p= 0.240).

On third day after clustered care there was a no reduction in the mean HR(144.82±4.29) as compared to the pretest HR which was statistically not significant(t=1.855,p= 0.079) which shows that there was a significant improvement of heart rate on third day on physiological parameters of preterm care . However the heart rate was within normal limits.

Similarly the mean RR before clustered care was (49.79±5.98). On first day after clustered care the mean RR was (47.60. ±4.92), (t=5.34p<0.001), which is statistically significant.

On second day also there was a slight reduction in the mean RR46.07±4.69 as compared to pretest. RR (46.07±4.69), which is statistically significant. (p<0.001).

On third day after clustered care there was significant improvement in RR (44.41±4.50) as compared to pretest RR which was statistically significant (t=8.81,p<0.001). These findings reveals clustered care was effective in reducing, the respiratory rate of preterm care.

Regarding of oxygen saturation before clustered care was 95.43±2.34. On first day after clustered care the mean Spo2 was (97.93±0.84), (t= 5.62, p<0.001). Which is statistically significant.

On second day there was slight improvement in mean oxygen saturation as compared to pretest was (98.54±0.72), ($t=5.69$, $p<0.001$), which is statistically significant.

On third day after clustered care there was significant improvement in mean oxygen saturation was (99.06±0.80), ($t= 6.57$, $p<0.001$).which is also statistically significant. These findings reveals clustered care was effective in improving the oxygen saturation on all 3days.

It is evident from these findings of clustered care was effective in enhancing the physiological parameters of preterm care.

The overall mean of post test score of preterm care, In terms of physiological parameters there was no significant different in the HR in all three days. In respiratory rate significant difference was found in second day (46.07±4.69), $p<0.001$) and in third day (44.41±4.50), $p<0.001$). However in oxygen saturation post test score was found highly significant on all three days (99.06±0.80) $p<0.001$). From these results it can be inferred the Clustered care did not cause stress in terms of physiological parameters and newborn born between 32-37 weeks of gestation were able to tolerate clustered care.

Hence the null hypothesis was rejected and research hypothesis was accepted.

Table: 4.2. 4 Comparison of pre and post median range (IQR) of comfort score of neonates on preterm care n=20

Comfort Score	No. of Days		Z Wilcoxon Sign Rank Test			
				Morning	Afternoon	Night
1.Alertness	**Pre test**		Median (IQR)	2(2-3)	2(2-3)	2(2-2)
	Day – 1	**Post test**	Median Test score CI (95%) P –Value	2(2-2) 2.652 0.000-.139 0.008	2(2-2) -2.810 0.000-.139 0.005*	2(1-2) -3.500 0.000-.139 0.001**
	Pre test		Median(IQR)	2(2-3)	2(2-3)	2(2-2)
	Day – 2	**Post test**	Median Test score CI (95%) P –Value	2(1-2) -2.810 0.00-.139 0.005*	1(1-2) -3.320 0.00-.139 0.001**	1(1-1) -3.573 0.000-.139 0.001**
	Pre test		Median(IQR)	2(2-3)	2(2-3)	2(2-2)
	Day – 3	**Post test**	Median Range Test score CI(95%) P –Value	1(1-2) -3.568 0.000-.139 0.001**	1(1-1) -3.862 0.000-.139 0.001**	1(1-1) -4.177 0.000-.139 0.001**
2.Calmness	**Pre test**		Median (IQR)	3(2-3)	3(2-3)	2(2-3)
	Day – 1	**Post test**	Median Test score CI(95%) P –Value	2(2-2) -3.153 0.000-.139 0.001**	2(2-2) -3.120 0.000-.139 0.002	2(1-2) -2.138 0.000-.139 0.033
	Pre test		Median(IQR)	3(2-3)	3(2-3)	2(2-3)
	Day – 2	**Post test**	Median Test score CI(95%) P –Value	2(2-2) -3.358 0.000-.139 0.001**	2(1-2) -3.640 0.000-.139 0.001**	1(1-2) -3.234 0.000-.139 0.001**
	Pre test		Median(IQR)	3(2-3)	3(2-3)	2(2-3)
	Day – 3	**Post test**	Median (IQR) Test score CI(95%) P –Value	1(1-2) -3.611 0.000-.139 0.001**	1(1-1) -3.817 0.000-.139 0.001**	1(1-1) -3.874 0.000-.139 0.001**
3.Physical Movement	**Pre test**		Median(IQR)	3(2-3)	3(2-3)	2(2-3)
	Day – 1	**Post test**	Median Test score CI(95%) P –Value	2(2-2) -3.638 0.000-.139 0.001**	2(2-2) -3.464 0.000-.139 0.001**	2(2-2) 3.000 0.000-.139 0.003
	Pre test		Median(IQR)	3(2-3)	3(2-3)	2(2-3)
	Day – 2	**Post test**	Median Test score CI (95%) P –Value	2(2-2) 3.466 0.000-.139 0.001**	2(1-2) -3.704 0.000-.139 0.001**	1(1-2) -3.704 0.000-.139 0.001**
	Pre test		Median(IQR)	3(2-3)	3(2-3)	2(2-3)
	Day – 3	**Post test**	Median Range Test score CI(95%) P –Value	2(1-2) 3.471 0.000-.139 0.001**	1(1-2) 3.640 0.000-.139 0.001**	1(1-1) 3.906 0.000-.139 0.001**

Note:*p<0.005, **p<0.0001.

Alertness: 1-Deeply asleep, 2-Lightly asleep, 3- Drowsy, 4- Fully awake and alert, 5- Hyper alert.

Calmness/agitation: 1- Calm, 2- Slightly anxious, 3-Anxious, 4- Very anxious, 5- Panicky.

Physical movement: 1- No movement, 2- Occasional, slight movement, 3-Frequent slight movement, 4- Vigorous Movement, 5- Vigorous movements including torso and head.

In this section the comfort level of the preterm care was compared before and after clustered care.

Wilcoxon sign rank test was used to compare the median comfort scores with Inter Quarterlies range within the group from day 1 to day 3 at morning, afternoon and night shift according to the number of clusters. To test the comfort level within the group at various time intervals the null hypothesis was formed.

Null hypothesis (Ho_6) There will be no significant difference in pre and post test of comfort score on clustered care among preterm care.

Table 4.2.4 shows the median comfort scores before and after clustered care from day 1 to day 3.

As shown in table 4.2.4 before clustered care the preterm care were in slightly asleep state in the morning 2(2-3), afternoon 2(2-4)and night 2(2-2) respectively.

Alertness:

On the first day 2 clusters (4-5 procedures) in the morning the preterm newborn remained in lightly asleep state 2(2-2) as compared to pretest and was found to be statistically significant CI (0.000-.139, $p<0.008$).In the afternoon and in the night they remained in slightly asleep state 2(2-2).which was also statistically significant CI (000.139, $p<0.005$).

Similarly on second day regarding alertness state the preterm newborn ranged from slightly asleep 2(1-2) in the morning to deeply asleep state in the afternoon 1(1-1) and during the night 1(1-1) which is statistically significant ($p<0.001$).

On third day the preterm newborn constantly remained in the state of deeply asleep state, morning 1 (1-2) afternoon1 (1-1) and night1 (1-1) respectively CI (0.000-.139, $p<0.001$).

Calmness:

Similarly with regard level of calmness before clustered care preterm newborn in were in anxious state 3 (2-3) in the morning, remain same state in afternoon and anxious state 3(2-3), and in the night the state of alertness improved to slightly anxious 2(2-3).

On 1st day after 4 and 5 clustered care in the morning the preterm care were in slightly anxious state 2(2-2)as compared to pretest and was found to be statistically significant CI(0.000-.139p<0.001), in the afternoon 2(2-2) and also during night remained slightly anxious state. 2(1-2), CI (0.000-.139, p<.0.033).

Similarly on second day the preterm newborn were in slightly anxious in morning 2(2-2) when compared to pretest median score the calmness state was same in afternoon 2(1-2).This was also sustained in night 2(1-2), (CI 0.000-.139, p<0.001), which was also statistically significant.

On third day also the preterm newborn constantly were in calm state during morning 1(1-2) afternoon1 (1-1) and night1 (1-1) respectively (CI (0.000-.139, p<0.001).

Physical movement:

In terms of physical movement before clustered care preterm care were in frequent slight movement state 3(2-3) in the morning, in afternoon they were in state remain frequent slight movement 3(2-3) and night the state of calmness was occasional slight movement 2(2-3) CI (0.000-.139, p<0.003).

On 1st day of clustered care clustered care in the morning the preterm newborn were in occasional slight movement 2(2-2)as compared to pretest and was found to be statistically significant CI(0.000-.139p<0.001),in the afternoon 2(1-2) and night also remain in state of occasional slight movement 2(2-2),CI(0.000-.139,p<.001). Which was also statistically significant.

Similarly on second day the physical movement state preterm newborn were in occasional slight movement 2(2-2) in the morning .when compared to pretest median score the physical movement state was constant in afternoon and night 2(1-2) at CI 0.000-.139,p<0.001).

On third day the physical movement score compared to the post test state of occasional slight physical movement after clustered care preterm newborn were in the state of no movement in morning 1(1-2) afternoon1 it was improved to no movement 1(1-1) and night also remain in same state 1 (1-1) (CI (0.000-.139, p<0.001).

The above findings reveal that the clustered care was effective in maintaining comfort of preterm newborn. From these findings it can be infered that clustered care, enhanced level of comfort and improved alertness from the level of fully awake state to deeply asleep state, calmness improved from state of anxious to calm state and physical movement improved from frequent slight movement to no movement state. Hence it can concluded that clustered care was effective in improving the comfort level of preterm newborn. Hence the null hypothesis is rejected and research hypothesis is accepted.

CHAPTER-V

RESULTS AND DISCUSSION

The clustered care is combing several routine nursing care events together rather than spacing them out over the time. The study aimed to examine the effect of clustered care on physiological parameters, stress, and comfort level among preterm newborn on phototherapy, and preterm care. Clustered care with combining four or five procedures performed together at various time intervals in preterm newborn.

This chapter deals about the discussion of the study with appropriate Statistical analysis and the finding based on the objectives and hypothesis. The study was a quasi experimental (multiple time series design with repeated institution of treatment) .The problem stated as "to assess the effectiveness of clustered care on physiological parameters, stress, and comfort level among preterm newborn admitted in NICU tertiary care settings, Coimbatore.

Among 40 preterm newborn, in which 20 are assigned as phototherapy group and 20 are assigned to preterm care. Samples were selected by non probability purposive sampling method. The study was conducted among the preterm newborn admitted in NICU in a tertiary care settings, Coimbatore.

Pre and Post test was conducted by using modified NISS –to assess the stress of preterm newborn , physiological parameters of heart rate, respiratory rate and oxygen saturation by using Philips pulse oxymeter, and comfort level were assessed by modified comfort scale. For three days and three times with various time intervals at morning, afternoon, and night respectively.

5.1 Demographic profiles of Preterm newborn on Phototherapy, and preterm care:

In the present study the preterm newborn who were born between 32-37 weeks of gestation among them 11 (55%) were in phototherapy and 13(65%) were in Preterm care.

Among 40 preterm newborn who received clustered care .In phototherapy group 9(45%) were delivered by LSCS and 11(55%) were delivered by normal vaginal delivery and in the preterm care the newborn delivered by normal vaginal delivery 10(50%) and LSCS 10(50%) were equal in both the groups. In contrast to study on comparison of clustered care with three

and four procedures by literature had 22(71%) neonates delivered by LSCS. (**(Liston F, A, 2015).**

The current study reveals that, more than half of 11 (55%) preterm newborn on phototherapy had a birth weight of 2.1kg to 2.5 kgs. However majority 13 (65%) of preterm care newborn birth weight between 1.5kg to 2kgs.These findings are different to another study on comparison of clustered care with three and four procedures on physiological response to preterm infants with minimum weight of 1000gms. (**Shafagh Fallan et al., 2012).**

The duration of hospitalization was 4-7 days in the present study .The findings are similar to another study where preterm newborn's hospitalization was 5-8 days. **(Hamilton K E Stc., 2008)**

5.1.3 Comparison of pre and post test of NISS scores of preterm newborn on phototherapy

In the present study, NISS score before clustered care was 23 with a mean of (16.8±1.77), afternoon (10.7±0.923), and at night (12.5 ±2.02). After clustered care there was a significant reduction in NISS score of all three days at various time intervals in the morning (D1-13.5 ±1.10, D2-11.75, D3-10. 15±1.41).similarly in afternoon (D1-10.9 ±1.53, D2- 9.5 ±1.5, D3-8.85 ±1.38),and at night (D1-11.5 ±1.70, D2 -10.25 ±1.58, D3 -9 ±1.46). There was no significant difference in the physiological parameters. In the present study the newborn clustered care 2 in the morning with 4-5 procedures and the stressor score were (11) and (12) and afternoon 1 cluster was formed stressor score (11), night 1 cluster stressor score (15).

The above findings are similar to another study with total of 31 preterm newborn were studied at two times, one time clustered care with three procedures(7 stressor score) and other time clustered care with four procedures (10 stressor score).the study results conclude that there was no statistical difference across the three phases of clustered care with 7 stressor score(t=2.93,p,0.071), and three phases of clustered care with 10 stressor score (t=0.24,p,0.742). as no significant difference with three non invasive procedures stress score performed clustered care with seven and ten stressor score .so, the amount of stress can be assumed acceptable for such infants **(Marziyeh Avazeh 2014).**

5.1.4 Comparison of pre and post test score of physiological parameters of preterm newborn on phototherapy.

In this present study, there was a significant improvement in the physiological parameters of preterm newborn phototherapy who received clustered care, the overall mean of post test score in terms of physiological parameter was significant difference on third day in heart rate($t=2.45 p<0.023$),and in respiratory rate significant difference found in second day($t=3.18$, $p<0.004$),and in third day($t=6.02. p<0.001$).However in oxygen saturation post test score was found highly significant on all three days (D1-$t= 3.69$ $p<0.001$), (D2- $t=3.18$, $p<0.004$),and on third day ($t= 4.19$ $p<0.001$).These results reveals that Clustered care was effective in maintaining the normal physiological parameters of preterm newborn on phototherapy.

In the present study there were significant reduction of HR, RR after clustered care it was maintained within normal limits .None of the preterm newborn developed bradycardia and bradypnea and the sao_2 improved from pretest to post test. These findings are similar to KMC for clustered pain procedures of heel prick and injection reported that clustered painful procedures were tolerated with no bradycardia and o_2 desaturation during Kangaroo care. **(Raouth R. Kostandy, 2016).**

5.1.5 Comparison of pre and post mean score of comfort scale of preterm newborn on phototherapy.

The present study has demonstrated that clustering of invasive and non invasive procedures at various time intervals like morning, afternoon and night minimized frequent handling and there by increased comfort of the preterm newborn .A statistically significant difference was found before and after clustered care for 3 days. Before clustered care alertness state 2(2-3) in lightly asleep (2). Post test was in deeply asleep1 (1-1) ($Z=3.753, p<0.001$). Calmness-anxious state 3 (3-4), ($Z=-3.387$, $p<0.001$) post test as calm 1(1-2). Physical movement median score on comfort before clustered frequent movement state 3(2-3),$p<0.004$) no movement 1(1-1) ($z=3.894, p<0.001$).

Similar findings are reported by Raouth R.Kostandy 2016 on effectiveness of KMC on clustered invasive procedures by Anderson Behavioral state scoring system showed during heel prick and injection the infants were predominantly in sleep state. **(Raouth R . Kostandy 2016).**

5.2.2 Comparison of pre and post test of NISS scores of neonates on preterm care.

In this present study, there was a significant improvement in the stress reduction of preterm group on clustered care, from base line pretest morning mean score 17.25 ($t=3.176, p<0.005$) to third day as evidenced by reduced in stress and post test mean score was 13.45($t=5.728, p,<0.001$), which is statistically significant difference found with pretest. In the afternoon from base line pretest afternoon mean score 11.4($t=2.179, p<0.042$) to third day post test mean score was 9.859$t=5.615, p<0.001$).In the night from base line pretest mean score 13 ($t=0.256, p<0.008$) to third day post test mean score was 10($t=5.29, p<0.001$).This findings reveals that the stress level were reduced when compared to before and after clustered care on each day .It is found that the clustered care was effective in reduction of stress among preterm group and frequent handling was minimized.

The above findings are similar to another study which was done among the healthy newborn to assess the effects of pain, stress during invasive procedures. This study shows that there is increase in stress while disturbing frequent handling with < 32 weeks of gestational weeks**. (Shoaib Ali Khan, 2011).**

5.2.3 Comparison of pre and post test score of physiological parameters of neonates on preterm care.

In this present study, there was a significant improvement in the physiological parameters of preterm group who received clustered care, from the first day before HR was 144.76 and after 144.82($t=1.855$). There was slight difference in heart rate of preterm group. Similarly RR before 47.72 and after 44.99($t=8.81, p<0.001$). Which is statistically significant. In oxygen saturation, before 97.67($t=5.62$) and after 99.08.($t= 6.57, p<0.001$).However it is statistically significant. These findings found to be adequate oxygen saturation was maintain in preterm group. Clustered care did not cause desaturation .The preterm newborn could tolerate clustered care of 5-6 procedures. The HR did not vary significantly on all three days. All parameters were within normal limits.

The above finding varies from another study on comparison of clustered care with three and four procedures physiological responses of preterm group. These results shows that heart rate before, during, after of three procedures were 146.26, 149.90, 149.97.and five procedures were 150.61, 154.77, 154.65. Respiratory rate of three procedures were respectively. In this study HR,RR and spo2 was measures 2 minutes before ,during and after 2 minutes of clustered care and the enrolled were preterm with RDS. 51.68, 48.87, 47.71, and five procedures were 49.10, 48.61,49.48.oxygen saturation after the clustered care with procedures were respectively 97.52,97.32,97.84 and in clustered care with five procedures were 97.68,97.94,97.65**. (Marziyeh Avazeh 2014).**

In the present study the physiological parameters were measured only after each clustered care in the morning, afternoon and night .More over preterm newborn with RDS were not included in the study and the gestational age was 32-37 weeks.

5.2.4 Comparison of pre and post mean score of comfort scores of neonates on preterm care.

The current study shows that the median alertness observation before clustered care of was in lightly asleep (2) Whereas after clustered care were in deeply asleep state 1(1-1) ($Z=-4.177$, $p<0.001$)

With regard to calmness median score on comfort level before clustered care in the morning was in anxious state3 (2-3), ($Z=-3.153$, $p<0.001$). As compared to pretest calmness score based on the number of procedures 5 clustered there was a further improvement in comfort median score calmness was improved with the state of calm 1(1-2) ($z=-3.874$,$p<0.001$). In terms of physical movement median score on comfort level before clustered care median range was in frequent movement state 3(2-3), ($z=-3.638$, $p<0.001$).As compared to pretest calmness score based on the number of procedures were reduced with 4 cluster. There was a improvement in physical movement with state of no movement 1(1-1) ($z=3.960$, $p<0.001$). Which is statistically significant $p<0.001$.

The overall comfort level of three components on alertness, calmness and physical movement of preterm care newborn was compared with pretest , post test stressor were less and Comfort level was improved with all three days with various time intervals subsequently morning, afternoon and at night with $p<0.005$. These findings are similar to another study on quality of life of preterm newborn nineteen preterm babies with gestational age 30 weeks, Where 15 preterm infants were classified as median score state of anxious 3(1-3) to state of calm 1(1-2), and four were moving calmly to very agitate in NICU admission. **(Joke.M Weilenga., 2012).**

CHAPTER-VI

SUMMARY AND CONCLUSION

The present study was conducted to assess the effectiveness of clustered care on physiological parameters, stress, and comfort level among preterm newborn in tertiary care settings, Coimbatore.

Research design used in this study was quantitative research approach quasi experimental, multiple time series design with repeated institution of treatment. The purposive sampling technique was used in this study. The sample size was 40 preterm newborns who are admitted in the level II of NICU. Out of which 20 preterm newborns are in phototherapy group, and another 20 are in preterm care newborn. According to the selection criteria the preterm newborn were selected from the tertiary care setting, Coimbatore. Modified NISS scale was used to assess the stress level, pulse oxymeter was used to check the physiological parameters, and modified comfort scale was used to measure the comfort level of both groups. The data was collected after the approval of the ethical committee.

The data was collected through observation check list of both preterm newborn on phototherapy, preterm care newborn. Both descriptive and inferential statistics were used for analyses of the data. Paired "t" test was used to compare the effectiveness of clustered care on physiological parameters, stress, and comfort level of preterm newborn on phototherapy and preterm care newborn. Z wilcoxon signed rank test used to compare the pre post assessment of median range of comfort scale for both the groups. $\chi 2$ test was used to find out the association between selected demographic variables with comfort level in preterm newborn on phototherapy, preterm care newborn.

6.1 Major finding of the study:

- The age of preterm newborn ranged from 0-3 days, 12(60%) in the photherapy group and 13(65%) in preterm care group.
- Majority of 17 (85%) preterm newborn on phototherapy and 14 (70%) preterm care newborn were hospitalized for 4-7 days.

- Regarding the experience of the NICU Nurses the minimum experience was 6 months-1 year 6 (30%) was in preterm newborn on phototherapy ,nearly 10(50%) of the nurses who were caring the preterm care newborn had more than 3 years of experience.

- There was reduction in stress level of preterm newborn on phototherapy in the morning (11.5 ±1.10) afternoon (9.85 ±0.67) and during the night (9 ±1.46) ($p<0.001$). In Preterm care in the morning (15.6 ±1.67) afternoon (10.6 ±1.57) and at night (10.8 ±0.93) there was a significant reduction in mean NISS score ($p<0.001$).

- The statistical analysis revealed that, no significant difference in the HR of clustered care on physiological parameters of HR in preterm newborn on phototherapy before (144.76± 4.57) and after clustered care (D_1 - 144.09± 4.57,D_2 -143.39±3.18, and D_3 -142.86 ± 3.32) in preterm care newborn (D_1 - 146.11± 5.41 D_2 - 145.86±4.69, and D_3-144.82 ± 4.29).no statistical difference

- There was significant difference found in mean RR in preterm newborn on phototherapy before (45.72 ± 2.3) and after clustered care for three days (D_1-45.24±2.08, D_2 244.16±1.83 and D_3 -42.99±1.76) in preterm care (D_1 47.60±4.92, D_2, 46.07±4.69 and D3 44.41 ±4.50) ($p<0.001$).

- There was a significant improvement in the mean spo_2 rate before clustered care (96.67±2.36) and after clustered care on all three days ($D\text{-}_1$ 98.13± 1.07, $D\text{-}_2$ 98.24±0.99 and ($D\text{-}_3$ 99.08 ± 1.05) in preterm care ($D\text{-}_1$ 97.93± 0.849, $D\text{-}_2$ 98.54±0.729 and $D\text{-}_3$ 99.06 ± 0.80) ($p<0.001$).

- The clustered care increases the comfort of the baby in the level of alertness fully awake state (4) to deeply asleep state (1), regarding calmness anxious state (3) to calm state (1) and physical movement frequent slight movement state(3) to no movement state(1).

- There was no association between selected demographic variables and the pre-test level of comfort level among preterm newborn on phototherapy, and preterm care.

6.2 Conclusions:

It is the fact that preterm newborn in NICU experience stress. Management of stress and altered sleep pattern will affect the preterm newborn brain development. The findings of the study shows that clustered care is effective in keeping the preterm newborn comfortable and maintain the physiological parameters and reduces the stress by avoiding frequent handling. Hence it is concluded that initiation of clustered care on preterm newborn that helps to reduce the stress level and improve the comfort level thereby the normal physiological parameters were maintained.

6.3 Nursing implications:

Nurses play a crucial role in taking care of preterm newborn to maintain the appropriate growth and development. The present study has implications for nursing practice, nursing education, nursing administration and nursing research.

Nursing practice:

- Nurses in NICU should be trained to handle the preterm newborns frequently.
- Nurses must develop specific skills, on clustered care in NICU procedures to minimize stress, and discomfort level among preterm newborn.
- Appropriate training can be provided to the novice staff nurses in NICU on the basis of improving their nursing skill towards preterm newborn care.

Nursing education:

- Clustered care should be included in Neonatal Nursing Curriculum during the course of study period to build up their competency.
- In-service education regarding the importance and effectiveness of the clustered care can be conducted to the staff nurses.
- Nurse educator can conduct a work shop on clustered care among preterm newborn.

Nursing Research:

- ✦ The neonatal nurses should be motivated in doing research studies with other disease condition.
- ✦ A comparative study can be done among preterm newborn with invasive and noninvasive procedure in NICU**.**

Nursing administration:

- ☐ Nurses in tertiary care centre have to include clustered care as a routine practice among preterm newborn.
- ☐ Opportunity should be given to the nursing staff to assess the effectiveness of clustered care practice.
- ☐ Prepare the policies and procedures related to clustered care in NICU.

6.4 Limitations:

- The study could not be done round the clock though the clusters were formed for each shift
- The total number of handlings for one day for each preterm newborn could be not observed.
- The study findings cannot be generalized to preterm with gestation age of 27-32 weeks and low birth weight, since preterm care newborns for thermoregulation and phototherapy were included.

6.5 Recommendations:

- The study can be conducted in a larger group of population
- Similar study can be conducted among 28-32 weeks of gestational age of preterm newborn.

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ANNEXURE-I

PSG COLLEGE OF NURSING, COIMBATORE-4.

Ref.No: CN/I/103/17

Date: 04.07.2017

To

The Dean
PSG IMSR&H
Peelamedu
Coimbatore.

Respected Sir,

Sub: Permission to conduct research req.reg

Warm Greetings!

This is to inform you that Mrs. D. Jeyamoni, I year M.Sc Nursing student of our College of Nursing, Coimbatore is planning to conduct a study on

"A Study to Assess the Effectiveness of Clustered Care in Terms of Enhancing Physiological Parameters, Stress Level and Comfort among Preterm Newborn Admitted in NICU in a Tertiary Care Setting, Coimbatore"

as part of M.Sc(N) research requirement to be submitted at The Tamilnadu Dr. M.G.R Medical University, Chennai.

Kindly grant her permission for conducting pilot & Main study in our Hospital. We assure you that the study will be conducted without disturbing the routine activities of the Hospital.

Thanking you,

4/7/17

Dr. A. JAYASUDHA
PRINCIPAL

PSG COLLEGE OF NURSING Peelamedu COIMBATORE-4

Cc to: The HOD, Dept of NICU
The Nursing Superintendent

Can be done but only with Ethics approval. Thank you

6/7

PSG COLLEGE OF NURSING, COIMBATORE-4.

Ref.No: CN/I/103/17

Date: 04.07.2017

To

The Dean
PSG IMSR&H
Peelamedu
Coimbatore.

Respected Sir,

Sub: Permission to conduct research req.reg

Warm Greetings!

This is to inform you that Mrs. D. Jeyamoni, I year M.Sc Nursing student of our College of Nursing, Coimbatore is planning to conduct a study on

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Kindly grant her permission for conducting pilot & Main study in our Hospital. We assure you that the study will be conducted without disturbing the routine activities of the Hospital.

Thanking you,

4/7/17

Dr. A. JAYASUDHA
PRINCIPAL

PSG COLLEGE OF NURSING * Peelamedu * COIMBATORE-4

Cc to: The HOD, Dept of NICU
The Nursing Superintendent

Permitted to do the study

20.7.17

ANNEXURE-II

PSG Institute of Medical Sciences & Research
Institutional Human Ethics Committee
Recognized by The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)
POST BOX NO. 1674, PEELAMEDU, COIMBATORE 641 004, TAMIL NADU, INDIA
Phone : 91 422 - 2598822, 2570170, Fax : 91 422 - 2594400, Email : ihec@psgimsr.ac.in

To
Ms D Jeyamoni
I M Sc Nursing
PSG College of Nursing
Guide/s: Dr G Malarvizhi / Dr S Ramesh
Coimbatore

Ref: Project No.17/233

Date: October 27, 2017

Dear Ms Jeyamoni,

Institutional Human Ethics Committee, PSG IMS&R reviewed and discussed your application dated 21.07.2017 to conduct the research study entitled "*A study to assess the effectiveness of clustered care in terms of enhancing physiological parameters, stress level and comfort among preterm newborn admitted in NICU, tertiary care setting*" during the IHEC review meeting held on 22.09.2017.

The following documents were reviewed and approved:

1. Project Submission form
2. Study protocol (Version 2 dated 24.10.2017)
3. Parental consent form (Version 1 dated 21.07.2017)
4. Data collection tool (Version 2 dated 24.10.2017)
5. Permission letter from the Dean and concerned Head of Department
6. Current CVs of Principal investigator, Co-investigators
7. Budget

The following members of the Institutional Human Ethics Committee (IHEC) were present at the meeting held on 22.09.2017 at College Council Room, PSG IMS & R between 2.30 pm and 4.00 pm:

Sl. No.	Name of the Member of IHEC	Qualification	Area of Expertise	Gender	Affiliation to the Institution Yes/No	Present at the meeting Yes/No
1	Mrs Y Ashraf	MPT	Physiotherapy	Female	Yes	Yes
2	Dr. S. Bhuvaneshwari (Member-Secretary, IHEC)	MD	Clinical Pharmacology	Female	Yes	No
3	Mr Gowpathy Velappan	BA., BL	Legal Advisor	Male	No	Yes
4	Dr A Jayavardhana	MD	Clinician (Paediatrics)	Male	Yes	Yes
5	Mr P Karuppuchamy	M Phil in PSW	Social Scientist	Male	Yes	Yes
6	Dr G Malarvizhi	M Sc, Ph D	Nursing	Female	Yes	Yes
7	Mr. R. Nandakumar (Chairperson, IHEC)	BA., BL	Legal Expert	Male	No	Yes

8	Dr. Parag K Shah	DNB	Clinician (Ophthalmology)	Male	No	Yes
9	Mrs P Rama	M Pharm	Non-Medical (Pharmacy)	Female	Yes	No
10	Dr. Seetha Panicker	MD	Clinician (Obstetrics & Gynaecology)	Female	Yes	No
11	Dr. S. Shanthakumari	MD	Pathology, Ethicist	Female	Yes	Yes
12	Dr. Sudha Ramalingam (Alternate Member-Secretary, IHEC)	MD	Public Health, Epidemiology, Genetics, Ethicist	Female	Yes	Yes
13	Mrs. Swasthika Soundararaj	MBA	Lay person	Female	No	Yes
14	Dr. D. Vijaya	M Sc, Ph D	Basic Medical Sciences (Biochemistry)	Female	Yes	Yes

The study is approved in its presented form. The decision was arrived at through consensus. Neither PI nor any of proposed study team members were present during the decision making of the IHEC. The IHEC functions in accordance with the ICH-GCP/ICMR/Schedule Y guidelines. The approval is valid until one year from the date of sanction. You may make a written request for renewal / extension of the validity, along with the submission of status report as decided by the IHEC.

Following points must be noted:

1. IHEC should be informed of the date of initiation of the study
2. Status report of the study should be submitted to the IHEC every 12 months
3. PI and other investigators should co-operate fully with IHEC, who will monitor the trial from time to time
4. At the time of PI's retirement/intention to leave the institute, study responsibility should be transferred to a colleague after obtaining clearance from HOD, Status report, including accounts details should be submitted to IHEC and extramural sponsors
5. In case of any new information or any SAE, which could affect any study, must be informed to IHEC and sponsors. The PI should report SAEs occurred for IHEC approved studies within 7 days of the occurrence of the SAE. If the SAE is 'Death', the IHEC Secretariat will receive the SAE reporting form within 24 hours of the occurrence
6. In the event of any protocol amendments, IHEC must be informed and the amendments should be highlighted in clear terms as follows:
   a. The exact alteration/amendment should be specified and indicated where the amendment occurred in the original project. (Page no. Clause no. etc.)
   b. Alteration in the budgetary status should be clearly indicated and the revised budget form should be submitted
   c. If the amendments require a change in the consent form, the copy of revised Consent Form should be submitted to Ethics Committee for approval
   d. If the amendment demands a re-look at the toxicity or side effects to patients, the same should be documented
   e. If there are any amendments in the trial design, these must be incorporated in the protocol, and other study documents. These revised documents should be submitted for approval of the IHEC and only then can they be implemented

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POST BOX NO. 1674, PEELAMEDU, COIMBATORE 641 004, TAMIL NADU, INDIA
Phone : 91 422 - 2598822, 2570170, Fax : 91 422 - 2594400, Email : ihec@psgimsr.ac.in

f. Any deviation-Violation/waiver in the protocol must be informed to the IHEC within the stipulated period for review

7. Final report along with summary of findings and presentations/publications if any on closure of the study should be submitted to IHEC

Thanking You,

Yours Sincerely,

SECRETARY
PSG IMS&R
COIMBATORE-641004
INSTITUTIONAL HUMAN ETHICS COMMITTEE

Dr D Vijaya
Member - Secretary
Institutional Human Ethics Committee

ANNEXURE-III

SOP 03-V 3.0 / ANX 10-V 3.0

Institutional Human Ethics Committee

PSG Institute of Medical Sciences and Research, Coimbatore

Parental Consent Form

Title of Study: "A STUDY TO ASSESS THE EFFECTIVENESS OF CLUSTERED CARE IN TERMS OF ENHANCING PHYSIOLOGICAL PARAMETERS, STRESS LEVEL AND COMFORT AMONG PRETERM NEWBORN ADMITTED IN NICU ,TERRITORY CARE SETTING**".**

Name of the Principal Investigator: D. Jeyamoni

Department: M.sc Nursing I Year Child Health Nursing Department.

Your preterm newborn infant is invited to participate in a study of to assess the effectiveness of clustered care in terms of enhancing physiological parameters ,stress level and comfort among preterm newborn admitted in NICU, territory care setting, Coimbatore .

My name is D.Jeyamoni and I am a M.sc Nursing I Year Student at PSG College of Nursing, Coimbatore. This study is part of my partial fulfillment of M.sc Nursing Program.

The justification for this study is:

- Because the preterm infant's brain is very immature and is easily affected by external stimuli .All forms of sensory input to the immature brain of a preterm infant influences long term development. Because stress affects sleep. Lack of sleep, sleep cycle maturation negatively influence development of the brain .clustered care is designed to minimize the stress of the neonatal unit environment. A clustered care approach can lead to a number of concrete benefits for the infant. Promote weight gain, shorter hospital stay, better growth.

I am asking for permission to include your preterm newborn in this study because in this study, as a principle investigator I am going to provide clustered care and to observe the physiological parameters, stress level and comfort among preterm newborn will be assess through NISS scale, COMFORT scale.

I expect to have 40 preterm newborn participate in the study.
who admitted in NICU PSG Hospital.

Any information that is obtained in connection with this study and that can be identified with your preterm newborn will remain confidential and will be disclosed only with your permission. His or her responses will not be linked to his or her name or your name in any written or verbal report of this research project.

Your decision to allow your preterm newborn to participate will not affect your or his or her present or future relationship with PSG IMS&R or PSG Hospitals . If you have any questions about the study, please ask me. If you have any questions later, call me at any time. If you have any questions or concerns about your preterm newborn participation in this study, call 7708047949

You may keep a copy of this consent form.

You are making a decision about allowing your preterm newborn to participate in this study. Your signature below indicates that you have read the information provided above and have decided to allow him or her to participate in the study. If you later decide that you wish to withdraw your permission for your preterm newborn to participate in the study, simply tell me.

You may discontinue his or her participation at any time. *This will not affect in any way your future treatment in this hospital.*

Signature of Parent(s) or Legal Guardian with Date Signature of Investigator with Date

பூ சா கோ மருத்துவக் கல்லூரி மற்றும் ஆராய்ச்சி நிறுவனம். கோவை

மனித நெறிமுறைக் குழு

பெற்றோர் ஒப்புதல் படிவம்

<u>ஆய்வின் தலைப்பு:</u>

பச்சிளம் குழந்தைகளின் தீவிர சிகிச்சை பிரிவின் கீழ் குறைப்பிரசவத்தில் பிறந்து சிகிச்சை பெரும் பச்சிளம் குழந்தைகளின் உடல்நிலையை ஒருங்கிணைந்து கவனிப்பதன் மூலம் குழந்தையின் உடலியக்கம், அழுத்தத்தின் அளவு, சௌகர்யம், போன்றவற்றை பற்றிய ஆய்வு.

டே.ஜெயமோனி ஆகிய நான் பூ.சா.கோ செவிலியர் கல்லூரியில் குழந்தைகள் நல பிரிவு துறையின் கீழ் முதுநிலை செவிலியர் பட்டப்படிப்பு படிக்கிறேன்

நான் தங்களின் குழந்தையை ஒருங்கிணைந்து கண்காணிப்பதன் மூலம் குழந்தைகளின் அழுத்தம் குறைந்து, உறக்கம், சௌகர்யம் எவ்வாறு மேம்பாடடைகிறது என்பதனை ஆய்வின் மூலம் கண்டறிய தங்களின் ஒத்துழைப்பை வேண்டுகிறேன்.

<u>ஆய்வு மேற்கொள்வதன் அடிப்படை</u>

- தற்போதுள்ள பயிற்சியின் மூலம் குறிப்பிட்ட சில நோய்களுக்கு, சமகால இடைவெளியில் செவிலியர்களால் எவ்வாறு கண்காணிக்கப்படுகிறது.

- குறைமாத குழந்தைகளின் குறிப்பிட்ட நோய்களுக்கு, தற்போதைய கண்காணிக்கும் பயிற்சிக்கும், ஒருங்கிணைந்து கண்காணிக்கும் பயிற்சிக்கும் உள்ள குழந்தைகளின் அழுத்தத்தின் அளவை மதிப்பிட.

- ஒருங்கிணைந்து கண்காணிப்பதற்கு முன்பும், பின்பும் குழந்தையின் உறக்கம் மற்றும் சௌகர்யம் ஆகியவற்றில் உள்ள வித்தியாசம்.

- குறைமாத குழந்தையின் அழுத்த அளவை, குழந்தையின் உறக்கம் மற்றும் சௌகர்யம் ஆகியவற்றை தேர்ந்தெடுக்கப்பட்ட புள்ளி விவர அடிப்படையில் இணைத்துப் பார்த்தல்.

நான் இந்த ஆய்விற்காக தங்களின் ஒத்துழைப்பை வேண்டுகிறேன். ஏனெனில் இந்த ஆய்வின் தொடக்கத்தில் நான் தங்கள் குழந்தையின் அடிப்படைத் தகவல்களை சேகரிப்பேன். முதலில் குழந்தையின் செயல் திறன் கண்காணிக்கப்பட்டு, பின்பு தங்களின் குழந்தையை ஒருங்கிணைந்து கண்காணிப்பதன் மூலம் குழந்தைகளின் அழுத்தம் குறைந்து, உறக்கம், சௌகர்யம் எவ்வாறு மேம்பாடடைகிறது என்ற ஆய்வு செய்யப்படும்.

ஆய்வில் பங்குபெறுவதற்கான நிபந்தனைகளில் நிறைவு செய்யப்பட்ட 40 குழந்தைகள் மட்டும் ஆய்வில் ஈடுபடுத்த படுவார்கள்.

ஆய்வில் பங்கு பெறுவதால் எற்படும் பலன்கள்:

- **நோய்த்தொற்றிலிருந்து பாதுகாத்தல்,**
- **குழந்தையின் உறக்கம் மற்றும் சௌகர்யம் மேம்படுத்தல்**
- **விரைவான உடல்நிலை முன்னேற்றம்**

ஆய்வில் பங்குபெறுவதால் எற்படும் அசௌகரியங்கள் / பக்கவிளைவுகள் : ஏதுமில்லை.

இந்த ஆய்வின் கேள்விகளுக்கு பதிலளிப்பதில் உங்களுக்கு ஏதெனும் அசௌகரியங்கள் இருந்தால், எந்த நேரம் வேண்டுமானாலும் ஆய்விலிருந்து விலகிக்கொள்ளும் உரிமை உங்களுக்கு உண்டு. ஆய்விலிருந்து விலகிக்கொள்வதால் உங்களுக்கு எந்த வித பாதிப்பும் இருக்காது என்று உறுதியளிக்கிறோம்.. நீங்கள் அளிக்கப்படும் தகவல்கள் இரகசியமாக வைக்கப்படும். இந்த ஆய்வில் பங்கேற்பவர்கள் பற்றிய எந்தத் தகவலும் எக்காரணம் கொண்டும் வெளியிடப்படாது என்று உறுதியளிக்கிறோம். நீங்கள் அளிக்கப்படும் தகவல்கள் அங்கீகரிக்கப்பட்ட ஆய்விற்கு மட்டுமே பயன்படுத்தப்படும். உங்களுக்கு ஏதேனும் இந்த ஆய்வினைப் பற்றிய சந்தேகம் அல்லது கேள்விகள் இருப்பின் உடனடியாகவோ அல்லது தொலைப்பேசி மூலமோ தொடர்பு கொள்ளவும் - (77080 47949)

ஒப்புதல்:

இந்த ஆய்வைப் பற்றிய மேற்கூறிய தகவல்களை நான் படித்து அறிந்துகொண்டேன் / ஆய்வாளர் படிக்க கேட்டுத் தெரிந்துகொண்டேன். ஆய்வினைப் பற்றி நன்றாகப் புரிந்து கொண்டு இந்த ஆய்வில் என் குழந்தையை ஈடுபடுத்த ஒப்புக் கொள்கிறேன். இந்த ஆய்வில் பங்கேற்பதற்கான எனது ஒப்புதலை கீழே கையொப்பமிட்டு / கைரேகை பதித்து தெரிவித்துக் கொள்கிறேன்.

பங்கேற்பாளரின் பெற்றோரின் பெயர், முகவரி :

பங்கேற்பாளரின் பெற்றோரின் கையொப்பம் / கைரேகை / சட்ட பூர்வ பிரதிநிதியின் கையொப்பம் :

தேதி:

ஆய்வாளரின் கையொப்பம் :

தேதி:

ஆய்வாளரின் தொலைபேசி எண்: 77080 47949

மனித நெறி முறைக் குழு அலுவலகத்தின் தொலைபேசிஎண்: 0422 2570710 extn: 5818.

ANNEXURE-IV

SECTION A:

DEMOGRAPHIC PROFILES - PRETERM NEWBORN ON PHOTOTHERAPY

Sample Number:

1. Days

- ☐ 0-3 days
- ☐ 4-7 days

2. Gender

- ☐ Male
- ☐ Female

3. Weight of the newborn at birth

- ☐ 1.5-2kgs
- ☐ 2-2.5kgs

4. Gestational age of the preterm newborn

- ☐ 32-34 weeks
- ☐ 35 -37 weeks

5. Mode of delivery

- ☐ Normal vaginal delivery
- ☐ Lower segment caesarian section

6. Duration of the hospitalization

- ☐ 0-3 days
- ☐ 4-7 days

7. Experience of the staffs in NICU

- ☐ 6 months-1year
- ☐ 1.1-2 years
- ☐ 2.1-3 years
- ☐ Above 3 years

ANNEXURE-IV

SECTION B: PHYSIOLOGICAL PARAMETERS

1. WEIGHT OF THE BABY:

2. VITAL SIGNS:

S. No	Physiological Parameters	Pre Test			Day 1			Day 2			Day3		
		MN 7-9 am	AN 1-3 pm	NT 7-9 pm	M 7-9 am	AN 1-3 pm	N 7-9 pm	M 7-9 am	AN 1-3 pm	N 7-9 pm	M 7-9 am	AN 1-3 pm	N 7-9 pm
1.	Heart Rate												
2.	Respiratory Rate												
3.	Spo_2												

ANNEXURE-IV

SECTION C: NISS TOOL

Appendix A

NICU Infant Stressor Record Sheet (<28 weeks).

Name: _____

INSTRUCTIONS: Enter the time that the procedure was performed (eg: 9:15 am) Date: _____

Acute Items	7am–9am	9am–11am	11am–1pm	1pm–3pm	
extremely stressful (score 5)					
Multiple attempts inserting IV, IA, UAC/UVC					
Intubation					
Insertion pneumothorax chest drain					
Eye examination					
very stressful (score 4)					
Suctioning of ETT tube					
Suctioning of nose and mouth					
Removing infant from incubator/bed (unwrapped)					
Insertion of IV, IA, UAC/UVC					
Insertion of percutaneous long line					
Insertion of nasal CPAP tube					
Lumbar puncture					
Surgery					
Heel pricks					
moderately stressful (score 3)					
Nappy changes					
Position changes					
Removal of IV					
Receiving nasal CPAP					
Insertion of Hudson Prong					
Insertion of nasogastric tube					
Gavage feed					
Removing infant from incubator/bed (wrapped)					
Cardiac echocardiogram					
Ultrasound					
CT/MRI					
X-ray					
Being weighed					
a little stressful (score 2)					
Mouth care					
Eye toilet					
IV Flushing (to ensure IV patency)					
Sampling eg. blood gases					
Removal of UAC/UVC					
Stomach aspiration via NGT					
ECG					
Attachment of monitor sensors					
Application of cream to body					
TOTAL ACUTE STRESS SCORE					

Chronic Items	
extremely stressful (score 5)	
very stressful (score 4)	
having asystemic infection	
HFO/Jet vent without sedation	
moderately stressful (score 3)	
nursed in radiant warmer	
local infection	
HFO/Jet vent with sedation	
Hudson Prong CPAP	
fasting for surgery	
recovering from surgery	
pneumothorax chest drain	
conventional ventilation w/o sedation	
a little stressful (score 2)	
nursed in incubator	
IV fluids	
IV/IA/UAC/UVC in situ	
conventional ventilation with sedation	
lumber puncture recovery	
intranasal oxygen	
head box oxygen	
nasogastric tube in situ	
phototherapy	
TOTAL CHRONIC STRESS SCORE	

*Not stressful: Intermittent NGT feed, bottle feed, cup feed, breast feed, receiving solution via UAC/UVC, receiving cot oxygen, continuous nasogastric feeding, being jaundiced.

ANNEXURE-IV

SECTION D: MODIFIED COMFORT SCORE-PRETERM NEWBORN ON PHOTOTHERAPY

S.No	COMFORT SCALE	Pre test			Day 1			Day 2			Day 3		
		Timings			Timings post test								
		MN 7-9 am	AN 1-3 pm	NT 7-9 Pm	M 7-9 am	AN 1-3 pm	N 7-9 pm	M 7-9 am	AN 1-3 pm	N 7-9 pm	M 7-9 am	AN 1-3 pm	N 7-9 pm
1	**Alertness**												
	Deeply asleep												
	Lightly asleep												
	Drowsy												
	Fully awake												
	Hyper-alert												
2	**CALMNESS/AGITATION**												
	Calm												
	Slightly anxious												
	Anxious												
	Very anxious												
	Panicky												
3	**PHYSICAL MOVEMENT**												
	No movement												
	Occasional, slight movement												
	Frequent, slight movement												
	Vigorous movement limited to extremities												
	Vigorous movements including torso and head												
	SCORE												

Alertness: Deeply asleep – 1, lightly asleep – 2, Drowsy - 3, fully awake and alert - 4, Hyper alert- 5

Calmness/agitation: Calm- 1, Slightly anxious - 2, Anxious – 3, Very anxious – 4, Panicky -5

Physical movement: No movement- 1 Occasional, slight movement- 2Frequent, slight movement -3Vigorous movement- 4 Vigorous movements including torso and head - 5

ANNEXURE-IV

SECTION A: DEMOGRAPHIC PROFILES OF PRETERM CARE

Sample Number:

1. Days

- ☐ 0-3 days
- ☐ 4-7 days

2. Gender

- ☐ Male
- ☐ Female

3. Weight of the newborn at birth

- ☐ 1.5-2kgs
- ☐ 2-2.5kgs

4. Gestational age of the preterm newborn

- ☐ 32-34 weeks
- ☐ 35 -37 weeks

5. Mode of delivery

- ☐ Normal vaginal delivery
- ☐ Lower segment caesarian section

6. Duration of the hospitalization

- ☐ 0-3 days
- ☐ 4-7 days

7. Experience of the staffs in NICU

- ☐ 6 months-1year
- ☐ 1.1-2 years
- ☐ 2.1-3 years
- ☐ Above 3 years

ANNEXURE-IV

SECTION B: PHYSIOLOGICAL PARAMETERS NEONATES ON PRETERM CARE

1. WEIGHT OF THE BABY:

2. VITAL SIGNS:

S. No	physiological parameters	Pre test			Day 1			Day 2			Day3		
		MN 7-9 am	AN 1-3 pm	NT 7-9 pm	M 7-9 am	AN 1-3 pm	N 7-9 pm	M 7-9 am	AN 1-3 pm	N 7-9 pm	M 7-9 am	AN 1-3 pm	N 7-9 pm
1.	Heart Rate												
2.	Respiratory Rate												
3.	SpO_2												

ANNEXURE-IV

SECTION C: NISS TOOL

Appendix A

NICU Infant Stressor Record Sheet (<28 weeks).

Name: _____

INSTRUCTIONS: Enter the time that the procedure was performed (eg: 9:15 am) Date: _____

Acute Items		7am–9am	9am–11am	11am–1pm	1pm–3pm	
extremely stressful	**(score 5)**					
Multiple attempts inserting IV, IA, UAC/UVC						
Intubation						
Insertion pneumothorax chest drain						
Eye examination						
very stressful	**(score 4)**					
Suctioning of ETT tube						
Suctioning of nose and mouth						
Removing infant from incubator/bed (unwrapped)						
Insertion of IV, IA, UAC/UVC						
Insertion of percutaneous long line						
Insertion of nasal CPAP tube						
Lumbar puncture						
Surgery						
Heel pricks						
moderately stressful	**(score 3)**					
Nappy changes						
Position changes						
Removal of IV						
Receiving nasal CPAP						
Insertion of Hudson Prong						
Insertion of nasogastric tube						
Gavage feed						
Removing infant from incubator/bed (wrapped)						
Cardiac echocardiogram						
Ultrasound						
CT/MRI						
X-ray						
Being weighed						
a little stressful	**(score 2)**					
Mouth care						
Eye toilet						
IV Flushing (to ensure IV patency)						
Sampling eg. blood gases						
Removal of UAC/UVC						
Stomach aspiration via NGT						
ECG						
Attachment of monitor sensors						
Application of cream to body						
TOTAL ACUTE STRESS SCORE						

Chronic Items		
extremely stressful	**(score 5)**	
very stressful	**(score 4)**	
having asystemic infection		
HFO/Jet vent without sedation		
moderately stressful	**(score 3)**	
nursed in radiant warmer		
local infection		
HFO/Jet vent with sedation		
Hudson Prong CPAP		
fasting for surgery		
recovering from surgery		
pneumothorax chest drain		
conventional ventilation w/o sedation		
a little stressful	**(score 2)**	
nursed in incubator		
IV fluids		
IV/IA/UAC/UVC in situ		
conventional ventilation with sedation		
lumber puncture recovery		
intranasal oxygen		
head box oxygen		
nasogastric tube in situ		
phototherapy		
TOTAL CHRONIC STRESS SCORE		

*Not stressful: Intermittent NGT feed, bottle feed, cup feed, breast feed, receiving solution via UAC/UVC, receiving cot oxygen, continuous nasogastric feeding, being jaundiced.

ANNEXURE-IV SECTION D: MODIFIED COMFORT SCORE NEONATES ON PRETERM CARE

S.No	COMFORT SCALE	Pre test			Day 1			Day 2			Day 3		
		Timings			Timings post test								
		MN 7-9 am	AN 1-3 pm	NT 7-9 pm	M 7-9 am	AN 1-3 pm	N 7-9 pm	M 7-9 am	AN 1-3 pm	N 7-9 pm	M 7-9 am	AN 1-3 pm	N 7-9 pm
1	**Alertness**												
	Deeply asleep												
	Lightly asleep												
	Drowsy												
	Fully awake												
	Hyper-alert												
2	**CALMNESS/AGITATION**												
	Calm												
	Slightly anxious												
	Anxious												
	Very anxious												
	Panicky												
3	**PHYSICAL MOVEMENT**												
	No movement												
	Occasional, slight movement												
	Frequent, slight movement												
	Vigorous movement limited to extremities												
	Vigorous movements including torso and head												
	SCORE												

Alertness: Deeply asleep – 1, lightly asleep – 2, Drowsy - 3, fully awake and alert - 4, Hyper alert- 5

Calmness/agitation: Calm- 1, Slightly anxious - 2, Anxious – 3, Very anxious – 4, Panicky -5

Physical movement: No movement- 1 Occasional, slight movement- 2Frequent, slight movement -3Vigorous movement- 4

Vigorous movements including torso and head - 5

ANNEXURE -V

Intervention - Preterm newborn on phototherapy

Time Interval		Procedure performed	NISS Score	Frequency of Handling
7 -7-15 am	Morning	Sponge bath	2	Cluster I
		Monitoring Vital signs	2	
		weighing the baby	3	
		Attachment of sensor	2	
		Placing under phototherapy	2	
		Total score	**11**	
9-30 – 9.50 am		I.V Insertion	4	Cluster II
		Blood Collection	2	
		OG insertion	3	
		Nappy changing	3	
2 - 2.20 pm	Afternoon	**Total score**	**12**	
		Monitoring Vital signs	2	Cluster I
		Nappy changing	3	
		Eye shield covering	2	
		Attachment of sensor	2	
		Placing under phototherapy	2	
8-8.20 pm	Night	**Total score**	**11**	
		Monitoring Vital signs	2	Cluster I
		Monitoring Blood glucose	4	
		Nappy changing	2	
		Attachment of sensor	2	
		Eye shield covering	2	
		Placing under phototherapy	3	
		Total score	**15**	

Note: Not stressful—Intermittent NG feed, Bottle feed, Cup feed, Breast feed, Continuous nasogastric feeding

Intervention: Preterm newborn on phototherapy

- Observation was done on existing practice and it was noticed that the preterm newborn were handled frequently 5 times in the morning, 3 times in the afternoon and 3 times in the night. Since there is mounting evidence that repeated stress especially that occurs during the critical early period of newborn development, has a profound and long lasting effect on several physiological systems. Hence a checklist was prepared for administration of clustered care.
- The clustered care comprised of four or five procedures which were grouped together at various time intervals.
- In the morning 4-5 procedures which included both invasive and non invasive (monitoring vital signs, sponge bath, weighing the newborn, insertion of OG tube/OG feed, collecting blood sample) with 11+12 point stressor scale and the NISS score was 11+12.So it has been formed as two clusters with NISS score cluster 1=11, cluster 2=12.
- In the afternoon single clusters were formed (monitoring vital signs, OG feed/breast feed, nappy changing, eye shield covering, placing under phototherapy) and the NISS score was 11.
- At night also single cluster were formed (monitoring vital signs, monitoring blood glucose, OG feed/breast feed, eye shield covering placing under phototherapy)and the NISS score as 15.
- Depending upon the need and time the clusters were grouped into 4-5, 5-6 procedures. Each day the number of procedures was reduced and the number of handling the newborn also varied from each shifts, the newborns were handled two times instead of 5 times in the morning, single time instead of 3 times in the afternoon and single time instead of 3 times during night.
- Instructed the nurses to perform clustered care with four or five procedures together within 15 to 20 minutes time period. Stress, Physiological parameters and comfort level were evaluated.

ANNEXURE -V

Intervention – Neonates on preterm care.

Cluster Care				
Time Interval		Procedure performed	NISS Score	Frequency of Handling
7 - 7.15am	Morning	Sponge bath	2	Cluster I
		Monitoring Vital signs	2	
		weighing the baby	3	
		Attachment of sensor	2	
		Nesting, cling wrap	2	
		Total score	**11**	
9.30 – 9 .50 am		I.V Insertion	4	Cluster II
		Blood Collection	2	
		OG insertion	3	
		Nappy changing	3	
		Total score	**12**	
2 -2.20 pm	Afternoon	Monitoring Vital signs	2	Cluster I
		Eye care	2	
		Nappy changing	3	
		Attachment of sensor	2	
		Nesting, cling wrap	2	
		Total score	**11**	
8-8.20 pm	Night	Monitoring Vital signs	2	Cluster I
		Monitoring Blood glucose	4	
		Iv line removal	2	
		Nappy changing	2	
		Attachment of sensor	2	
		Nesting, cling wrap	3	
		Total score	**15**	

Note: Not stressful—Intermittent NG feed, Bottle feed, Cup feed, Breast feed, Continuous nasogastric feeding.

Intervention: Neonates on Preterm care

- Observation was done on existing practice and it was noticed that the preterm care were handled frequently 5 times in the morning, 3 times in the afternoon and 3 times in the night. Since there is mounting evidence that repeated stress especially that occurs during the critical early period of newborn development, has a profound and long lasting effect on several physiological systems. Hence a checklist was prepared for administration of clustered care.
- The clustered care comprised of four or five procedures which were grouped together at various time intervals.
- In the morning 4-5 procedures which included both invasive and non invasive (monitoring vital signs, sponge bath, weighing the newborn, insertion of OG tube/OG feed, collecting blood sample, nesting, cling wrap) with 11+12 point stressor scale and the NISS score was 11+12.So it has been formed as two clusters with NISS score cluster 1=11, cluster 2=12.
- In the afternoon single cluster were formed (monitoring vital signs, OG feed/breast feed, nappy changing, eye care, attachment of sensor, nesting, cling wrap) and the NISS score was 11.
- At night also single cluster were formed (monitoring vital signs, monitoring blood glucose, Iv line removal, nappy changing, attachment of sensor, nesting, cling wrap) and the NISS score as 15.
- Depending upon the need and time the clusters were grouped into 4-5, 5-6 procedures. Each day the number of procedures was reduced and the number of handling the newborn also varied from each shifts, the newborns were handled two times instead of 5 times in the morning, single time instead of 3 times in the afternoon and single time instead of 3 times during night.
- Instructed the nurses to perform clustered care with four or five procedures together within 15 to 20 minutes time period. Stress, Physiological parameters and comfort level were evaluated.

ANNEXURE-VI

MASTER CODING SHEET

PHOTOTHERAPY GROUP

S.No	1	Procedures	Score	PRETEST	post test - NISS SCORE		
					D1	D2	D3
1	**M**	Sponge bath	2				
2		Monitoring Vitals signs	2	2	2	2	2
3		weighing the baby	3	3	3	3	3
4		I.V Insertation	4	4			
5		Blood Collection	2	2	2	2	2
6		Nappy chaning	3	3	3	3	3
7		OG insertation	3				
8		Attachment of sensory Probe	2	2	2	2	
9		Placing under phototheraphy	2	2	2	2	
10			**23**	**18**	**14**	**14**	**10**
		Total					
1	**AN**	Monitoring Vitals signs	2	2	2	2	2
2		Nappy chaning	3	3	3		3
3		Eye shield covering	2	2	2	2	2
4		Attachment of sensory Probe	2	2	2	2	2
5		Placing under phototheraphy	2	2	2	2	2
			11	**11**	**11**	**8**	**11**
		Total					
1	**N**	Monitoring Vitals signs	2	2	2	2	2
2		Nappy chaning	3	3	3		3
3		Eye shield covering	2	2	2	2	
4		Attachment of sensory Probe	2	2	2	2	2
5		Placing under phototheraphy	2	2	2	2	
6		Monitoring Blood glucose	4	4	4	4	4
		Total	**15**	**15**	**15**	**12**	**11**

PRETERM CARE GROUP

S.No	1	Procedures	Score	PRETEST	post test - NISS SCORE		
					D1	D2	D3
1	**M**	Sponge bath	2	2	2		
2		Monitoring Vitals signs	2	2	2	2	2
3		weighing the baby	3	3	3	2	2
4		I.V Insertation	4				
5		Blood Collection	2		2	2	2
6		Nappy chaning	3	3	3		3
7		OG insertation	3			3	
8		Attachment of sensory Probe	2	2	2	2	2
9		nesting ,cling wrap	3	3	3	3	3
10			**24**	15	17	14	14
		Total					
1	**AN**	Monitoring Vitals signs	2	2	2	2	2
2		Nappy chaning	3	3	3	3	3
3		eye care	2	2	2	2	
4		Attachment of sensory Probe	2	2	2	2	2
5		nestig,cling wrap	3	3	3	3	3
			12	12	12	12	10
		Total					
1	**N**	Monitoring Vitals signs	2	2	2	2	2
2		Nappy chaning	3	3	3		3
3		nesting,cling wrap	3	3	3	3	
4		Attachment of sensory Probe	2	2	2	2	2
5		Monitoring Blood glucose	4	4	4	4	4
6		iv removel	4				
		Total	**18**	14	14	11	11

PRETERM NEW BORN ON PHOTOTHERAPY

physiological parameter (HEART RATE)

pretest	day-1	day-2	day-3
146.66	142.6	146	142.6
141.33	140	142	141.33
138.66	140	140.66	140.66
147.33	146	144	144
149.33	147.33	146.66	146
145.33	146	144	146
148.66	145.33	145.33	147.33
147.33	145.33	146	145.33
139.33	142.66	142	140.66
146	146.66	144.66	146
146.66	151.33	150.66	149.33
152.66	150.66	146.66	141.33
147.33	141.33	138.66	140.66
144.66	144.66	142	140.66
142.66	141.33	142	140.66
143.33	142.66	144	142.66
146.66	146	143.33	142
131.33	134	136	134.66
144	142.66	141.33	140
146	145.33	142	145.33

physiological parameter (RR)

pretest	day-1	day-2	day-3
44	44.3	42.66	42.66
43.3	42.66	42.66	40.66
45.33	44.66	44.66	44
44.66	44.66	45.33	41.33
47.33	46.66	44.66	42.66
49.33	49.33	46	44.66
47.33	45.33	44.66	44.66
47.33	46.66	44.66	41.33
45.33	47.33	46	44
47.33	44.66	45.33	44
45.33	46	45.33	44
47.33	46	41.33	40.66
43.33	46.66	43.33	42
47.33	46	42	43.33
40.66	41.33	42	42
45.33	42	41.33	40.66
46	42.66	43.33	45.33
50.66	48.66	48.66	47.33
42	44.66	44.66	42
45.33	44.66	44.66	42.66

physiological parameter (sp02)

pretest	day-1	day-2	day-3
99.33	99	99.33	99
99.66	99.33	100	100
97.33	100	98.66	98.66
94.66	98.33	99	98.66
92.66	98	98.33	98.66
96	98.66	99	100
97.33	97.66	97.66	100
99.66	99.66	99	99.66
99.66	99.33	98.33	99.33
96.33	97	97.66	97
93.33	97.33	98.33	100
97	97	96.66	98
96.33	97.33	97	96.66
98.33	98.33	96.66	98.33
92.66	96.33	96.66	100
96.66	98	98	98
99.66	99.33	99.33	100
96.33	97.66	99.33	100
93.33	96.33	97.66	99.66
97.33	98	98.33	100

NEONATES ON PRETERM CARE

pretest	day-1	day-2	day-3
145.3	146.6	146	145.3
138	137.3	138	136.6
145.3	143.3	143.3	142.6
147.3	144.6	144.6	144
160.6	155.3	154	153.3
132.6	142.6	141.3	142.6
146.6	145.3	143.3	145.3
146.6	146	147.3	147.3
143.3	144.6	142	142.6
157.3	148.6	143.3	141.3
154.6	154	153.3	151.3
142	143.3	143	142
155.3	154.6	152	144
136.6	141.3	144.6	140
144.6	140.6	146	145
133.3	136.6	141.3	142
156.6	152.6	144	144
150	144.6	144	144
154.6	150.2	152.6	150.6
158.6	150.2	153.3	152.6
147.455	146.11	145.86	144.82

pretest	day-1	day-2	day-3
58.6	53.3	52.6	51.3
55.3	50.6	47.3	46
54	50.6	46.6	45.3
54	50.6	48	46
47.3	44	44	42
52	51.3	46.6	43.3
58	54	54	51.3
44.6	44.6	40	40
46.6	43.3	43.3	42
57.3	52.6	50	50
45.3	44	44	40
47.3	44.6	42	40.6
50.6	50	46.6	42.6
58.6	55.3	55.3	52.6
52.6	53.3	52	51.3
42.6	42	44.6	42
42	42	42	40
44.6	43.3	40	42
42	42	42	40
42.6	40.6	40.6	40
49.795	47.6	46.075	44.415

pretest	day-1	day-2	day-3
93.3	96.6	99.6	99
99.6	99.6	100	100
93.3	98.3	98.6	99.6
94	98.6	99	98.6
96	98	98.3	98.3
97	98	99	99
90.6	96	97.6	100
96.3	97.3	99	99.3
95	97	98.3	99.3
94	99	99	100
99.3	98	98.3	99
97.6	98.3	98.6	98.6
95	98	98	98
97.3	98.3	97.3	100
98.3	98.6	97	98
93	97	98.6	97.6
95.6	98.6	99	99
96.6	97.6	98.6	100
93.6	98.3	98	100
93.3	97.6	99	98
95.435	97.935	98.54	99.065

COMFORT SCALE - PHOTOTHERAPY

ALERTNESS

pretest -Alertness				
sample	M	AN	N	mean
1	2	2	2	2
2	2	2	2	2
3	3	2	2	2
4	2	1	1	1
5	2	2	2	2
6	3	3	2	3
7	5	4	3	4
8	2	2	2	2
9	4	4	2	3
10	4	4	2	3
11	2	4	4	3
12	3	3	2	3
13	4	4	4	4
14	2	2	2	2
15	2	3	3	3
16	4	4	2	3
17	2	2	2	2
18	2	2	2	2
19	2	2	2	2
20	3	3	2	3

day 1 post test -Alertness				
M	A	N	mean	
2	2	1	2	
2	2	1	2	
2	1	1	1	
1	1	1	1	
2	2	2	2	
2	2	2	2	
2	2	2	2	
2	1	1	1	
3	2	2	2	
2	2	2	2	
2	2	2	2	
2	1	1	1	
2	2	2	2	
1	2	2	2	
1	2	2	2	
2	2	2	2	
2	2	1	2	
2	2	2	2	
2	1	1	1	

day 2 post test -Alertness			
M	AN	N	mean
2	1	1	1
2	1	1	1
2	1	1	1
1	1	1	1
2	1	1	1
2	1	1	1
2	2	1	2
2	1	1	1
2	2	2	2
1	2	1	1
2	2	1	2
2	1	1	1
2	2	1	2
1	1	2	1
1	1	2	1
1	1	1	1
2	1	2	2
1	1	1	1
1	1	1	1

day 3 post test Alertness			
M	AN	N	mean
1	1	1	1
1	1	1	1
2	1	1	1
1	1	1	1
2	1	1	1
2	1	1	1
2	1	1	1
1	1	1	1
2	1	1	1
1	1	1	1
1	1	1	1
1	1	1	1
2	2	1	2
1	1	2	1
2	2	1	2
1	1	1	1
1	1	1	1
1	1	1	1
2	1	1	1

CALMNESS

sample no	pretest -calmness			
	M	A	N	mean
1	2	1	1	1
2	2	2	2	2
3	2	2	2	2
4	2	3	2	2
5	3	2	2	2
6	2	2	2	2
7	3	3	3	3
8	4	3	3	3
9	3	3	3	3
10	4	4	2	3
11	3	3	2	3
12	4	4	3	4
13	4	3	2	3
14	3	3	3	3
15	2	1	2	2
16	3	3	2	3
17	3	3	3	3
18	3	3	2	3
19	3	3	2	3
20	2	2	2	2

day 1 post test -calmness			
M	AN	N	mean
1	1	1	1
1	1	1	1
1	1	2	1
1	2	2	2
2	1	1	1
2	1	1	1
2	2	2	2
1	2	2	2
2	2	2	2
2	2	2	2
3	2	2	2
2	2	2	2
4	2	4	3
2	2	2	2
2	2	2	2
2	2	2	2
2	2	2	2
1	1	2	1
2	2	2	2

day 2 post test -calmness			
M	AN	N	mean
2	2	1	2
1	1	2	1
2	2	3	2
1	1	1	1
1	1	1	1
2	2	2	2
2	2	2	2
1	1	1	1
2	1	1	1
2	2	2	2
2	2	2	2
2	2	1	2
2	2	2	2
2	2	2	2
1	1	1	1
2	1	2	2
2	2	2	2
2	2	1	2
1	1	1	1
2	2	3	2

day 3 post test -calmness			
M	AN	N	mean
2	1	1	1
2	1	1	1
1	1	1	1
1	1	1	1
2	1	1	1
1	1	1	1
1	2	1	1
1	1	1	1
1	1	1	1
2	1	1	1
2	1	1	11
2	1	1	1
2	1	1	1
1	1	1	1
1	1	1	1
2	1	1	1
2	1	1	1
1	1	1	1
2	1	1	1
1	1	1	1

PHYSICAL MOVEMENT

sample no	pretest - physical movement			
	M	AN	N	mean
1	2	2	2	2
2	1	1	1	1
3	2	1	1	1
4	2	3	2	2
5	2	2	2	2
6	3	2	2	2
7	3	3	2	3
8	3	2	2	2
9	4	3	3	3
10	3	3	3	3
11	3	4	3	3
12	4	3	3	3
13	4	4	3	4
14	3	2	2	2
15	2	3	2	2
16	3	2	3	3
17	3	2	2	3
18	2	2	2	2
19	3	3	2	3
20	2	1	1	1

day 1 post test -physical movement			
M	AN	N	mean
2	2	2	2
2	1	1	1
2	1	1	1
1	2	1	1
1	2	2	2
2	2	2	2
3	2	2	2
2	2	2	
3	2	3	3
3	3	2	3
2	2	2	2
3	3	2	3
4	3	3	3
2	2	2	2
2	2	1	1
2	2	2	2
2	2	2	2
2	2	2	2
2	1	1	1

day 2 post test - physical movement			
M	AN	N	mean
2	1	2	2
1	1	1	1
2	2	1	2
1	1	2	1
2	2	2	2
1	1	1	1
2	2	2	2
1	1	1	1
2	2	2	2
2	2	2	2
2	2	2	2
2	2	2	2
2	2	3	2
1	2	2	2
2	2	1	2
1	1	1	1
1	1	1	1
2	2	2	2
2	2	1	2

day 3 post test -physical movement			
M	AN	N	mean
2	1	1	1
1	1	1	1
2	2	1	2
2	1	1	1
2	1	1	1
1	1	1	1
1	2	1	1
1	1	1	1
1	1	1	1
2	1	1	1
2	1	1	1
1	1	1	1
2	2	1	2
1	1	1	1
2	1	1	1
1	1	1	1
1	1	1	1
1	1	1	1
2	2	1	2

COMFORT SCALE - PHOTOTHERAPY

ALERTNESS

pretest -Alertness

	M	AN	N	mean
1	2	2	2	2
2	2	1	2	2
3	2	2	2	2
4	3	3	2	3
5	3	2	2	2
6	4	3	2	3
7	2	2	2	2
8	2	4	3	3
9	2	4	2	3
10	3	3	2	3
11	2	2	2	2
12	1	2	2	2
13	4	4	3	4
14	3	4	2	3
15	2	2	2	2
16	2	2	2	2
17	2	4	4	3
18	4	3	3	3
19	2	2	2	2
20	4	2	2	3

day 1 post test -Alertness

M	AN	N	mean
2	2	1	2
2	2	1	2
2	2	1	2
2	2	1	2
2	2	1	2
2	2	1	2
2	1	1	1
2	2	2	2
2	2	2	2
2	2	1	2
2	2	2	2
2	2	2	2
2	2	2	2
2	3	2	2
1	2	2	2
1	1	1	1
2	2	2	2
3	3	2	3
2	1	2	2
2	2	2	2

day 2 post test -Alertness

M	AN	N	mean
2	1	1	1
2	2	1	2
2	1	2	2
2	1	1	1
2	1	1	1
2	1	1	1
2	2	2	2
2	1	1	1
1	1	1	1
2	1	1	1
1	1	1	1
2	2	1	2
2	2	1	2
2	2	2	2
2	1	1	1
1	1	2	1
2	1	1	1
2	2	1	2
2	1	1	1
2	3	2	2

day 3 post test -Alertness

M	AN	N	mean
1	1	1	1
1	1	1	1
1	1	1	1
2	2	1	2
1	2	1	1
1	1	1	1
1	1	1	1
1	1	1	1
1	1	1	1
1	1	1	1
2	1	1	1
2	1	1	1
1	1	1	1
2	2	1	2
1	1	1	1
2	1	1	1
1	1	1	1
2	2	1	2
1	1	1	1
2	2	1	2

CALMNESS

pretest -calmness

	M	AN	N	mean
1	3	3	3	3
2	2	2	1	2
3	3	2	2	2
4	2	2	1	2
5	2	2	2	2
6	3	3	2	3
7	2	2	2	2
8	3	3	2	3
9	2	2	2	2
10	2	2	2	2
11	4	3	3	3
12	3	3	2	3
13	3	3	2	3
14	3	3	3	3
15	3	3	2	3
16	2	2	2	2
17	3	4	4	4
18	4	4	3	4
19	2	2	2	2
20	3	3	3	3

day 1 post test -calmness

M	AN	N	mean
2	2	2	2
1	1	1	1
2	2	3	2
2	1	1	1
2	3	3	3
2	2	2	2
2	1	1	1
2	2	2	2
1	1	1	1
1	2	1	1
2	2	2	2
2	2	2	2
3	2	2	2
3	2	2	2
2	2	2	2
3	3	2	3
3	2	2	2
3	2	2	2
1	2	2	2
2	2	2	2

day 2 post test -calmness

M	AN	N	mean
1	1	1	1
2	2	1	2
2	2	3	2
2	1	1	1
2	2	2	2
2	2	1	2
2	1	1	1
2	2	1	2
1	1	1	1
2	1	1	1
2	1	1	1
2	2	1	2
2	1	1	1
2	2	2	2
2	1	1	1
2	1	2	2
2	2	2	2
2	2	2	2
2	2	2	2
2	2	2	2

day 3 calmness

M	AN	N	mean
1	1	1	1
2	2	1	2
2	1	1	1
1	1	1	1
2	2	1	2
2	2	1	2
1	1	1	1
1	1	1	1
1	1	1	1
2	1	1	1
1	1	1	1
1	1	1	1
1	1	1	1
2	1	1	1
2	1	1	1
2	1	1	1
2	2	2	2
2	1	1	1
1	1	1	1
2	1	1	1

COMFORT SCALE

pretest -physical movement

	M	AN	N	mean
1	3	2	2	2
2	2	2	2	2
3	3	3	2	3
4	2	2	2	2
5	2	2	2	2
6	3	3	2	3
7	3	3	3	3
8	3	3	3	3
9	3	3	3	3
10	3	2	2	2
11	4	3	3	3
12	3	3	2	3
13	4	3	3	3
14	1	1	1	1
15	3	3	2	3
16	2	2	2	2
17	4	4	3	3
18	3	3	3	3
19	3	3	2	3
20	2	2	2	2

day 1 post test -physical movement

M	AN	N	mean
2	2	2	2
1	2	1	1
2	2	2	2
2	2	2	2
2	2	2	2
2	2	2	2
2	2	2	2
2	2	2	2
2	3	2	2
2	2	2	2
2	2	2	2
2	2	2	2
3	2	2	2
1	1	1	1
2	2	2	2
2	1	1	1
3	3	3	3
3	2	2	2
2	2	2	2
2	2	1	2

day 2 post test -physical movement

M	AN	N	mean
2	2	2	2
2	2	2	2
2	1	1	1
1	1	2	1
2	2	1	2
2	2	1	2
2	2	1	2
2	1	1	1
2	2	1	2
1	1	1	1
2	2	1	2
1	1	1	1
2	2	2	2
2	2	2	2
2	1	1	1
2	1	1	1
2	2	2	2
2	2	1	2
2	1	1	1
1	1	1	1

day 3physical movement

M	AN	N	mean
2	2	1	2
2	2	2	2
2	2	1	2
2	2	1	2
1	1	1	1
1	1	1	1
2	1	1	1
2	1	1	1
2	2	2	2
1	1	1	1
1	1	1	1
1	1	1	1
2	1	1	1
1	1	1	1
2	1	1	1
2	2	2	2
2	1	1	1
1	1	1	1
1	1	1	1
1	1	1	1